

# **EPA Jacket 82552-1**

## **Vol.1**

Explore Registration					
Reg Number:	82552-R	Reg Type:	Product Registration - Section 3	Status:	Under Review (31-May-2005)
Name:	CONCROBIUM			<a href="#">&lt;View Registration Details&gt;</a>	
(No New Receipts)					
S	Submission Type	OPP Rec'd Date	Resubmission	Description	
<div> <div> <div>Decisions</div> <div> <div>Data Requirements</div> <div>Pending, 02-Jun-2005, 02-Jun-2005, A54, NEW PRODUCT N</div> </div> </div> <div> <div>Decision Sequence:</div> <div>357584</div> </div> <div> <div>Action:</div> <div>A54 NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM</div> </div> <div> <div>Number:</div> <div>82552-R</div> <div>Original Decision:</div> <div></div> </div> <div> <div>Name:</div> <div>CONCROBIUM</div> </div> <div> <div>Decision Status:</div> <div>PENDING (02-Jun-2005)</div> </div> <div> <div>Organization Owner:</div> <div>AD / RMB2</div> </div> <div> <div>Team Owner:</div> <div>RM 34</div> </div> <div> <div>FFS Start Date:</div> <div>22-Jun-2005</div> <div>Received by Risk Manager:</div> <div></div> </div> <div> <div>Due Date:</div> <div>19-Dec-2005</div> <div>FFS Amt Expected:</div> <div>\$4,000</div> </div> <div> <div>Negotiated Due Date:</div> <div></div> <div>FFS Amt Refunded:</div> <div></div> </div> <div> <div></div> <div>FFS Amt Received:</div> <div>\$4,000</div> </div> <div> <div>Comments:</div> <div></div> </div> </div>					



Adam  
Heyward/DC/USEPA/US  
01/25/2006 10:59 AM

To SHayes@srcconsultants.com  
cc Ann Cozad <acozad@srcconsultants.com>, Mark  
Hartman/DC/USEPA/US@EPA  
bcc  
Subject Re: Concrobium, EPA Reg. No. 82552-1

Hi Sally:

Thank you for informing me of the status of the data requirements as it relates to the conditions of registration for the product " Concrobium, EPA Reg. No. 82552-1". As requested, the Agency has approved your request for a 60-day extension.

A copy of this email will be added to the subject product file for future reference.

Best regards

Adam Heyward  
SHayes <SHayes@srcconsultants.com>



SHayes  
<SHayes@srcconsultants.com>  
m>

01/25/2006 09:55 AM

Please respond to  
SHayes@srcconsultants.com

To Adam Heyward/DC/USEPA/US@EPA  
cc Mark Hartman/DC/USEPA/US@EPA, Ann Cozad  
<acozad@srcconsultants.com>  
Subject Concrobium, EPA Reg. No. 82552-1

Adam,

On October 13, 2005 Siamons International, Inc. was granted a conditional registration for Concrobium, EPA Reg. No. 82552-1. One of the conditions was to conduct a GLP preliminary analysis study for submission by January 30, 2006. Siamons subsequently contracted Stillmeadow Laboratories to conduct a 5 lot analysis by HPLC. We have received the results; four of the results are slightly above the certified limits. We are investigating these results to determine if it is related to the method or if we need to request the the certified limits to accommodate this unexpected increase in the active ingredient.

Since we are still in the investigation mode, we are requesting a 60-day extension. We hope to have this resolved before then but this will allow time to conduct a new GLP study if needed.

Please let me know as soon as possible so we know how to move forward.

Thank you.

Sally Hayes  
Scientific & Regulatory Consultants, Inc.  
260-244-6270  
www.srcconsultants.com



front label



NOT REVIEWED  
In accordance with PR Notice 82-2.  
Based on Draft Labeling Dated

10/13/05

## back label peels back to more instructions



**Use Concrobium Mold Control** to seal mold in vulnerable areas such as basement, bathroom, closets and around windows. For use on hard surfaces such as wall, floor, wall, roof, masonry, concrete and tile.

### Ideal For

- > Mold remediation in basements and attics
- > Mold prevention following flooding or water damage cleanup
- > Pre-treatment of building materials for mold resistance

### DIRECTIONS FOR USE

**MOLD AND WATER CONTROL IN WOOD, WALLBOARD, CONCRETE AND MASONRY (GREEN) BLOCK CONSTRUCTION MATERIALS IN BUILDINGS**

Concrobium Mold Control is used to treat mold, mildew, moisture and masonry (concrete) block building materials to inhibit or prevent the growth of mold organisms when the materials are subjected to mold or wet environments. Before applying the product, visible mold growth must be removed and conditions favorable to mold growth must be identified and corrected.

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Read label before using.

### PREVENTATIVE TREATMENT

- 1) Apply Concrobium Mold Control to areas with mold or mildew.
- 2) To prevent drying and to reveal trussing marks, use a clean cloth or paper towel to wipe off excess product.
- 3) Allow treated surfaces to dry completely.

### REHEAT TREATMENT - SMALL AREAS - TOTAL SURFACE AREA AFFECTED LESS THAN 30 SQUARE FEET

Areas of visible growth of less than 30 square feet (the area of a single wall panel) can normally be remediated without elaborate procedures. When these areas are identified, apply Concrobium Mold Control to reveal growth and spread of fungal spores and other contaminants with the area can be thoroughly cleaned and remediated. If growth is on ceiling tiles or other such easily removable items of material, remove them and seal them in a plastic bag and dispose with normal trash. If the surface is not easily replaceable:

- 1) Clean contaminated area to remove surface soil. For best results, use a mild detergent to remove surface soil. After cleaning, use Concrobium Mold Control to inhibit cleaning. Use a cloth, cleaning pad or brush suitable to the material of the surface being cleaned. However, as much dirt and debris as possible.

- 2) Apply Concrobium Mold Control in desired area with evenly wet.
- 3) To prevent drying and to reveal trussing marks, use a clean cloth or paper towel to wipe off excess product.
- 4) Allow treated surface to dry completely.

Refer to the Personal Protection Equipment Requirements for Applicators section for the appropriate PPE to wear. Peel back label for large area remediation directions and storage and disposal instructions.

**Concrobium Mold Control** is suitable for use on most surfaces. It is ideal, perform a test on a small, inconspicuous surface. Identify vulnerable to water moisture and mold growth. Apply Concrobium Mold Control. Over application may cause some mold to become dormant, which can be easily wiped away with a Concrobium Mold Control-dampened cloth.

**Concrobium Mold Control** can be applied by hand-spray, paintbrush, roller, immersion, edging sprayer or pressure washer (approximately 1 gallon of product should treat a 400 sq. ft. area in a large). To maintain protection against re-growth, do not clean or wash surfaces after treatment. Reapplication of Concrobium Mold Control may be required if surfaces are washed or painted or in an otherwise directly exposed to water.

Ready to use - do not dilute. Concrobium Mold Control must come in direct contact with mold to be effective.

### Questions or Comments?

Contact: Customer Service, Science International Inc., 35 Main Street, Toronto, ON M9W 1A4, 1-866-611-4148 or at [www.concrobium.com](http://www.concrobium.com).  
 "Concrobium and Concrobium Mold Control are trademarks of Science International Inc., Toronto, Canada.  
 U.S. Patent Nos. 6,194,199 and 6,225,270. Other patents pending.  
 Made in Canada



Bar Code

PEEL BACK LABEL FOR MORE INSTRUCTIONS

### DIRECTIONS FOR USE (cont'd)

**REHEAT TREATMENT**  
 Concrobium Mold Control is designed to be used to prevent and inhibit the growth of mold, mildew and other fungi on walls, ceilings, floors, walls, window frames, and other hard non-porous surfaces with such items as the cases of such growth can be identified and corrected. This product should be used in those cases where visible mold growth has been detected (in conditions not likely to immediately result in such growth) as part of a comprehensive program that removes the growth and identifies and corrects the conditions that led to that growth, including:

- > Periodic monitoring and inspection of conditions favorable to mold growth such as moisture ingress and high relative humidity
- > Effective repairs as necessary to eliminate conditions favorable to mold growth
- > Drying of affected areas to below 70% relative humidity

**LARGE AREAS - TOTAL SURFACE AREA AFFECTED GREATER THAN 30 SQUARE FEET**  
 Areas larger than 30 square feet require special procedures, and individuals trained in remediation. Guidelines for remediation of large areas of contamination have been established by the Indoor Air Quality Association ([www.iaqa.org](http://www.iaqa.org)) and the U.S. Environmental Protection Agency ([www.epa.gov](http://www.epa.gov)).

Many in the field also refer to the New York City Department of Health, "Guidelines on Assessment and Remediation of Mold in Indoor Environments." Before using Concrobium Mold Control in mitigation of large projects, you should be knowledgeable of use or state of those guidelines and follow them when using the product. More information can be obtained from [www.concrobium.com](http://www.concrobium.com).

When water damage is suspected, the first priority is to find the source of the water and cut it off. Once that has been accomplished, excess water should be removed. Detailed guidance on proper removal of excess levels of water is contained in "Standard and Reference Guide for Professional Water Damage Restoration" (ICRC S500), published by the Institute of Inspection, Cleaning and Restoration Certification ([www.iirc.org](http://www.iirc.org)). If excess water has been removed completely in 24 hours or less, drying surfaces that were wet with Concrobium Mold Control will inhibit growth and no other steps should be necessary.

When structural members and/or contents have been exposed to water in excess of 24 hours, there is a possibility of extensive microbial growth that may be visible or hidden. In that case a complete assessment and remediation plan must be prepared that properly incorporates the use of Concrobium Mold Control, provides for proper and complete safety and decontamination and monitoring of the remediation process. If you are not experienced in preparing and executing such a plan, contact Concrobium Customer Service at 800-611-4148 for assistance. ICRC S500 contains excellent guidelines. In the context of such a plan, Concrobium Mold Control can be used as a mold inhibitor to be removed and disposed of and in other applications where an antifungal agent is indicated.

Refer to the Personal Protection Equipment Requirements for Applicators section for the appropriate PPE to wear.

### APPLICATION

Repeat application weekly or when growth or odor resumes. Prior to reapplication determine the cause of re-growth and correct that problem. Reapplication of Concrobium Mold Control may be required if surfaces are washed or painted or in an otherwise directly exposed to water.

**PERSONAL PROTECTION EQUIPMENT REQUIREMENTS FOR APPLICATORS**  
 For areas less than 30 sq. feet, use P-95 respirator, gloves and goggles/eye protection. For areas greater than 30 sq. feet, use P-95 respirator or half-face respirator with HEPA filter, disposable overalls, gloves and goggles/eye protection.

### STORAGE/DISPOSAL

Do not combine with water, food or feed by change or disposal.

**PRETREATMENT STORAGE:** Store in original container in cool, inaccessible to children. Keep securely closed.

**POSTTREATMENT DISPOSAL:** Periodic studies are available regarding long-term disposal of excess product, spray nozzles, or residue in a solution of related use. If these studies cannot be completed by you according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Response Division of the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:** Triple rinse (or equivalent). Then recycle or reclean, or puncture and dispose of in a sanitary landfill, or incineration, as it allowed by state and local authorities. Never, if burned, step out of canister.



front label



NOT REVIEWED  
In accordance with PR Notice 82-2.  
Based on Draft Labeling Dated

10/13/05

## back label peels back to more instructions



**Use Concrobium Mold Control** to control mold in vulnerable areas such as basement, bathroom, closets and travel trailers. For use on hard surfaces such as wallboard, plaster, wood, metal, masonry, concrete and brick.

### Ideal For

- > Mold remediation in basements and attics
- > Mold growing following flooding or water damage cleanup
- > Pre-treatment of building materials for mold resistance

### DIRECTIONS FOR USE

**WALL AND CEILING TREATMENT IN ROOMS, WALLBOARD, CONCRETE, AND MASONRY (GREEN BLOCK CONSTRUCTION MATERIALS IN BATHROOMS)**

Concrobium Mold Control is used to treat wood, wallboard, concrete and masonry (color) block building materials to inhibit or prevent the growth of mold organisms. The material is applied to moist or wet environments. Before applying the product, visible mold growth must be removed and conditions favorable to mold growth must be identified and corrected.

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Read label before using.

### PREVENTIVE TREATMENT

To inhibit the growth of mold and inhibit on surfaces:

- 1) Apply Concrobium Mold Control on areas with mold growth.
- 2) To prevent drying and to avoid residue marks, use a clean cloth or paper towel to wipe off excess residue.
- 3) Allow treated surfaces to dry completely.

**REMEDIAL TREATMENT - SMALL AREAS - TOTAL SURFACE AREA AFFECTED LESS THAN 30 SQUARE FEET**

Areas of visible mold growth of less than 30 square feet (the area of a single wall panel) can usually be remediated without elaborate procedures. When these areas are identified, apply Concrobium Mold Control to inhibit growth and spread of fungal spores and other contaminants and the area can be thoroughly cleaned and removed. If growth is on ceiling tiles or other such easily removable items of material, remove them and seal them in a plastic bag and dispose with normal trash. If the surface is not easily replaceable:

- 1) Once contaminated area is removed, surface can be treated with Concrobium Mold Control to inhibit future growth.
- 2) Once contaminated area is removed, surface can be treated with Concrobium Mold Control to inhibit future growth.

- 2) Apply Concrobium Mold Control on cleaned area until evenly wet.
- 3) To promote drying and to avoid residue marks, use a clean cloth or paper towel to wipe off excess residue.
- 4) Allow treated surfaces to dry completely.

Refer to the Personal Protection Equipment Requirements for Application section for the appropriate PPE to wear. Peel back label for large area remediation directions and storage and disposal instructions.

**Concrobium Mold Control** is suitable for use on most surfaces. It is applied as a wet spray or mist. Incompletely wetted, surfaces susceptible to water marks should be applied immediately after contact with Concrobium Mold Control. Over application may result in visible staining, which can be easily wiped away with a Concrobium Mold Control-damp cloth.

**Concrobium Mold Control** can be applied by hand-spray, paintbrush, roller, immersion, sprayer or pressure washer (approximately 1 gallon of product should treat a 400 sq. ft. area at 1.5 gpa). To achieve maximum mold growth, do not treat or wash surfaces after treatment. Application of Concrobium Mold Control may be required if surfaces are washed or painted or are otherwise directly exposed to water.

Ready to use - do not dilute. Concrobium Mold Control must come in direct contact with mold to be effective.

### Questions or Comments?

Contact: Customer Service, Concrobium International Inc., 35 Holman Drive, Toronto, ON M8W 1A4 1-866-911-4148 or at [www.concrobium.com](http://www.concrobium.com).  
 \*Concrobium and Concrobium Mold Control are trademarks of Concrobium International Inc., Toronto, Canada.

U.S. Patent Nos. 6,194,188 and 6,225,278. Other patents pending.

Made in Canada



Bar Code

PEEL BACK LABEL FOR MORE INSTRUCTIONS

## DIRECTIONS FOR USE (Cont'd)



**REMEDIAL TREATMENT**

Concrobium Mold Control is designed to be used to prevent and inhibit the growth of mold, fungi and other fungi on walls, ceilings, floors, window frames, and other hard non-porous surfaces and such items as the cases of mold growth can be identified and corrected. The product should be used in other cases where visible mold growth has been identified (or conditions are likely to immediately result in mold growth) as part of a comprehensive program that removes the growth and identifies and corrects the conditions that led to that growth, including:

- > Periodic monitoring and inspection of conditions favorable to mold growth such as water leaks and high relative humidity
- > Fixing leaks or water damage as soon as possible
- > Drying of affected areas to below 20% relative humidity

**LARGE AREAS - TOTAL SURFACE AREA AFFECTED GREATER THAN 30 SQUARE FEET**

Areas larger than 30 square feet require special procedures and instructions listed in remediation. Concrobium Mold Control is not intended for use on surfaces that have been contaminated by the mold. For Quality Assurance (see separate) and the U.S. Environmental Protection Agency (see separate).

Many of the mold spores in the home that City Department of Health, "Guidelines on Assessment and Remediation of Mold in Indoor Environments." Before using Concrobium Mold Control in mitigation of large projects, you should be knowledgeable of one or more of these guidelines and follow them when using the product. Many instructions can be obtained from your concrobium.com.

When water damage is suspected, the first priority is to limit the source of the water and cut it off. Once this has been accomplished, excess water should be removed. Detailed guidance on proper removal of excess water is contained in:

"Standard and Reference Guide for Professional Water Damage Restoration" (IICRC S500), published by the Institute of Inspection, Cleaning and Restoration Certification (www.iirc.org). It covers water loss and removal completely in 24 hours of loss, drying techniques that work best with Concrobium Mold Control and mold growth and the other steps should be necessary.

When structural members and/or contents have been exposed to water in excess of 24 hours, there is a possibility of extensive mold growth that may be visible or hidden. In that case a complete assessment and remediation plan must be prepared. This properly incorporates the use of Concrobium Mold Control products for mold and excellent safety and documentation and monitoring of the remediation process. If you are not experienced in preparing and executing such a plan, contact Concrobium Customer Service at 866-911-4148 for assistance. (USPS 5500)

Concrobium Mold Control is suitable for use in such a plan. Concrobium Mold Control can be used on materials to be removed and disposed of and in other applications where an antimicrobial use is indicated.

Refer to the Personal Protection Equipment Requirements for Application section for the appropriate PPE to wear.

### REAPPLICATION

Repeat application weekly or when growth or odor resumes. Prior to reapplication determine the cause of re-growth and correct that problem. Reapplication of Concrobium Mold Control may be required if surfaces are washed or painted or are otherwise directly exposed to water.

**PERSONAL PROTECTION EQUIPMENT REQUIREMENTS FOR APPLICATIONS**

For areas less than 30 sq. feet, an N-95 respirator, gloves and goggles/eye protection are recommended to avoid exposure to mold or mold spores. For areas greater than 30 sq. feet, an N-95 respirator or full-face respirator with HEPA filter, disposable gloves, goggles and goggles/eye protection.

### STORAGE/DISPOSAL

Store in original container. Do not store in airtight container. Store in original container. Store in original container. Store in original container.

**PESTICIDE STORAGE:** Store in original container in area inaccessible to small children. Keep securely closed.

**PESTICIDE DISPOSAL:** Pesticide wastes are safety hazardous. Larger quantities of waste should be disposed of by the manufacturer. If a violation of Federal law, it should be disposed of by the manufacturer. If a violation of Federal law, it should be disposed of by the manufacturer. If a violation of Federal law, it should be disposed of by the manufacturer.

**CONTAINER DISPOSAL:** Triple rinse (or equivalent). Then recycle or recoup, or puncture and dispose of in a sanitary landfill, or incinerate, or if allowed by state and local authorities, burn. If burned, stay out of smoke.





front label



The label for Concrobium mold control is split diagonally from the top-left to the bottom-right. The upper-left portion is orange and features a circular logo with the text "encapsulates" and "mold" around a central graphic. The lower-right portion is dark grey. The product name "concrobium" is written in a large, white, italicized sans-serif font, with "mold control™" in a smaller, white, sans-serif font directly below it. To the right of the product name, the text "FOR MOLD REMEDIATION AND PREVENTION" is printed in a small, white, sans-serif font. Below the product name, three bullet points are listed in white: "> Prevents and inhibits mold", "> Eliminates musty odors", and "> Contains no ammonia, bleach or VOCs". Further down, a table of ingredients is provided in white text. Below the table, the warning "KEEP OUT OF REACH OF CHILDREN" is printed in white, followed by the instruction "Directions for Use must be read completely prior to using this product." in a smaller font. At the bottom right, "Net Contents 1gallon" is printed in white. At the very bottom, small white text reads "Pawloski/Malawski EPA Reg. No. 82552-1 EPA Est. No. 082993-CAN-001 Sold by SIMONS INTERNATIONAL TORONTO, CANADA".

encapsulates  
mold

FOR MOLD REMEDIATION  
AND PREVENTION

**concrobium**  
mold control™

- > Prevents and inhibits mold
- > Eliminates musty odors
- > Contains no ammonia, bleach or VOCs

ACTIVE INGREDIENT  
Sodium Carbonate..... 0.95%  
OTHER INGREDIENTS..... 99.05%  
TOTAL..... 100.00%

**KEEP OUT OF REACH OF CHILDREN**  
Directions for Use must be read completely prior to using this product.

Net Contents 1gallon

Pawloski/Malawski EPA Reg. No. 82552-1 EPA Est. No. 082993-CAN-001 Sold by SIMONS INTERNATIONAL TORONTO, CANADA

NOT REVIEWED  
In accordance with PR Notice 82-2.  
Based on Draft Labeling Dated

10/13/05



back label label peels back to more instructions

**Concrobium Mold Control™** first on surface to create an invisible antimicrobial shield that resists mold and inhibits the growth of mold and fungal spores, prevents new growth and eliminates early signs. Concrobium Mold Control contains no bleach, ammonia, sodium or VOCs and is suitable for use on most surfaces. Odors and caustics.

**Use Concrobium Mold Control** to seal mold in vulnerable areas such as basements, bedrooms, closets and several windows. For use on hard surfaces such as wallboard, plastic, wood, metal, masonry, concrete and tile.

#### Ideal For

- > Mold remediation in basements and attics
- > Mold prevention following flooding or water damage cleanup
- > Pre-treatment of building materials for mold resistance

#### DIRECTIONS FOR USE

**MOLD AND MILDWORM CONTROL IN WOOD, WALLBOARD, CONCRETE AND MASONRY (CHALKED BLOCK CONSTRUCTION MATERIALS IN BUILDINGS)**

Concrobium Mold Control is used to treat wood, wallboard, concrete and masonry (chalked block building materials) to inhibit or prevent the growth of mold, mildew and fungi. The materials are subjected to mold or mildew in environments. Before applying the product, visible mold growth must be removed and conditions favorable to mold growth must be identified and corrected.

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

#### PREVENTATIVE TREATMENT

- To inhibit the growth of mold and mildew on surfaces:
- 1) Apply Concrobium Mold Control on areas with mold yet.
- 2) To prevent drying and to avoid random marks, use a clean cloth or paper towel to wipe off excess surface.
- 3) Allow treated surfaces to dry completely.

#### RENTAL TREATMENT - SMALL AREAS - TOTAL SURFACE AREA AFFECTED LESS THAN 30 SQUARE FEET

Areas of visible growth of less than 30 square feet (the area of a single wall panel) can normally be remediated without elaborate procedures. When these areas are identified, apply Concrobium Mold Control to inhibit growth and spread of fungal spores and other contaminants until the area can be thoroughly cleaned and remediated. If growth is on ceiling tiles or other such easily removable items (laminated vinyl, remove them and seal them in a plastic bag and dispose with normal trash. If the surface is not easily replaceable:

- 1) Clean contaminated area to remove surface soil. For best results, seal in seal possible interference from other chemicals, use Concrobium Mold Control for mold cleaning. Use a cloth, cleaning pad or brush suitable to the material of the surface being cleaned. Remove as much dirt and visible mold as possible.

- 2) Apply Concrobium Mold Control on cleaned area until evenly wet.
- 3) To prevent drying and to avoid random marks, use a clean cloth or paper towel to wipe off excess surface.
- 4) Allow treated surfaces to dry completely.

Refer to the Personal Protection Equipment Requirements for Application section for the appropriate PPE to wear.

Concrobium Mold Control is suitable for use on most surfaces. It is ideal, perhaps a bit in a small, inconspicuous section. Elsewhere, wherever a surface is contaminated, use Concrobium Mold Control. One application may be some cases need to make a second application, which can be easily added using a Concrobium Mold Control-impregnated cloth.

Concrobium Mold Control can be applied by hand-spray, sprayer, roller, immersion, direct spray or pressure washer (approximately 1 gallon of product should treat a 400 sq. ft. area in a large). In suitable conditions, apply to growth, do not then or wash surfaces after treatment. Reapplication of Concrobium Mold Control may be required if surfaces are washed or painted or are otherwise directly exposed to water.

Ready to use - do not dilute. Concrobium Mold Control must come in direct contact with mold to be effective.

#### Questions or Comments?

Contact: Customer Service, Concrobium International Inc., 35 Major Drive, Toronto, ON M9W 1A4, 1-800-411-4148 or at [www.concrobium.com](http://www.concrobium.com).  
"Concrobium and Concrobium Mold Control are trademarks of Concrobium International Inc., Toronto, Canada."

U.S. Patent Nos. 4,194,199 and 4,725,275. Other patents pending.  
Made in Canada

**concrobium**  
mold-control™

Bar Code

PEEL BACK LABEL FOR MORE INSTRUCTIONS

#### DIRECTIONS FOR USE (cont'd)

**RENTAL TREATMENT**  
Concrobium Mold Control is designed to be used to prevent and inhibit the growth of mold, mildew and fungi on floors, walls, window sills, ceilings, and other hard non-porous surfaces and seal them as the cause of mold growth can be identified and corrected. The product should be used in those cases where visible mold growth has been detected (or conditions are likely to immediately result in mold growth) as part of a comprehensive program that removes the growth and identifies and corrects the conditions that led to that growth, including:

- > Periodic monitoring and inspection of conditions favorable to mold growth such as moisture levels and high relative humidity
- > Eliminating sources of moisture that are conducive to mold growth
- > Drying of affected areas to below 75% relative humidity

**LARGE AREAS - TOTAL SURFACE AREA AFFECTED GREATER THAN 30 SQUARE FEET**  
Areas larger than 30 square feet require special procedures and techniques to avoid contamination. Guidelines for remediation of large areas of contamination have been established by the Indoor Air Quality Association (www.iaq.org) and the U.S. Environmental Protection Agency (www.epa.gov).

Many of the best data refer to the New York City Department of Health, "Guidelines on Assessment and Remediation of Fungal in Indoor Environments." Before using Concrobium Mold Control in mitigation of large projects, you should be knowledgeable of one or more of these guidelines and follow them when using the product. Many alternatives can be obtained from [www.concrobium.com](http://www.concrobium.com).

When water damage is suspected, the first priority is to limit the source of the water and call it off. Once this has been accomplished, excess water should be removed. Isolated guidelines on proper removal of excess levels of water is contained in "Standard and Reference Guide for Professional Water Damage Restoration" (ICRC S500, published by the Institute of Inspection, Cleaning and Restoration Certification (www.irc.org)). If excess water has been removed completely in 24 hours or less, drying surfaces that were wet with Concrobium Mold Control will inhibit growth and no other steps should be necessary.

When structural members and/or contents have been exposed to water in excess of 24 hours, there is a possibility of extensive microbial growth that may be visible or hidden. In this case a complete assessment and remediation plan must be prepared that properly incorporates the use of Concrobium Mold Control, provides for proper and accepted safety and decontamination and monitoring of the remediation process. If you are not experienced in preparing and executing such a plan, contact Concrobium Customer Service at 888-411-4148 for assistance. ICRC S500 contains excellent guidance in the context of such a plan. Concrobium Mold Control can be used in addition to be removed and disposed of and in other applications where no remediation is indicated.

Refer to the Personal Protection Equipment Requirements for Application section for the appropriate PPE to wear.

#### REAPPLICATION

Repeat application every 30 days or after re-spray. Prior to reapplication determine the cause of re-growth and correct that problem. Reapplication of Concrobium Mold Control may be required if surfaces are washed or painted or are otherwise directly exposed to water.

**PERSONAL PROTECTION EQUIPMENT REQUIREMENTS FOR APPLICATIONS**  
For areas less than 30 sq. feet, an H-45 respirator, gloves and goggles/eye protection are recommended to avoid exposure to mold or mold spores. For areas greater than 30 sq. feet, an H-45 respirator or full-face respirator with HEPA filter, disposable gloves, gloves and goggles/eye protection.

#### STORAGE/DISPOSAL:

Do not consume, drink, food or feed by change or disposal.

**PESTICIDE STORAGE:** Store in original container in areas inaccessible to small children. Keep securely closed.

**PESTICIDE DISPOSAL:** Pesticide wastes are strictly hazardous. Improper disposal of excess pesticide, spray mixture, or residue is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the hazardous waste representative of the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:** Triple rinse (or equivalent). Then recycle or reuse, or puncture and dispose of in a sanitary landfill, or incinerate, or if allowed by state and local authorities, burn. If burned, stay out of smoke.

**concrobium**  
mold-control™



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☒ Amendment  
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 82552-1	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Concrobium	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Siamons International, Inc. 36 Meteor Drive Toronto, Ontario Canada M9W 1A4 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated 10/13/05
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated 10/13/05	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Amend- Resubmission in response to agency letter of October 13, 2005. Three (3) copies of final printed labeling.

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Metal Plastic Glass Paper Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> on label	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Bob MacDonald		Title Agent for Siamons International, Inc.	
		Telephone No. (Include Area Code) (260) 244-6270	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Agent for Siamons International, Inc.	
4. Typed Name Bob MacDonald		5. Date 1/18/06	

# CONCROBIUM

EPA Reg. No. 82552-1

## TRANSMITTAL DOCUMENT

1. Name and address of submitter:

Scientific & Regulatory Consultants, Inc.  
PO Box 1014  
Columbia City, IN 46725

AGENT FOR:  
Siemons International, Inc.  
36 Meteor Drive  
Toronto, Ontario M9W 1A4

2. Regulatory action in support of which this package is submitted:

Amendment (AMEND) – Final Printed Labeling in response to Agency letter  
dated October 13, 2005

3. Transmittal date: January 18, 2006

4. Vol. 1 Administrative materials:

- A) Cover letter
- B) Copy of Agency Letter (dated 10/13/05)
- C) Application
- D) Three (3) copies of labeling

Company Official: Bob MacDonald

Company Name: Agent for Siemons International, Inc.

Company Contact: Bob MacDonald

**SRC**  
**Scientific & Regulatory**  
Consultants, Inc.

January 18, 2006

Mr. Adam Heyward, PM 34  
Document Processing Desk (AMEND)  
Office of Pesticide Programs (7504C)  
U. S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1801 South Bell Street  
Arlington, VA 22202-4501

SUBJECT: Final Printed Labeling  
Concrobium  
EPA Reg. No. 82552-1

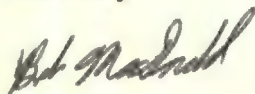
Dear Adam,

On behalf of our client Siamons International, Inc. ("Siamons") enclosed is "Final Printed Labeling" for the above mentioned registration. This is being submitted in response to your agency letter of October 13, 2005.

**PLEASE NOTE:** This label is consistent with the agency stipulations in your October 13, 2005 correspondence and the recent labeling notification supplied to you on November 22, 2005 (accepted on December 5, 2005). However, since this final printed labeling does not itself include all of the optional text currently found acceptable and on file with the EPA for this registration we request that you do not post this version on the PPLS system. Naturally we wish to maintain the "master label" optional text in our clients file for any future labeling revision.

Thank you for your assistance on this matter. If you have any questions please contact me at (260) 244-6270 or by e-mail at bmacdonald@srcconsultants.com.

Sincerely



Bob MacDonald  
Agent for Siamons International, Inc.

cc: E. Green

P.O. Box 1014  
Columbia City, IN 46725

[www.srcconsultants.com](http://www.srcconsultants.com)

Phone: 260-244-6270  
Fax: 260-244-6273





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

December 5, 2005

Bob MacDonald  
Scientific & Regulatory Consultants, Inc.  
Agent for **Siamons International, Inc.**  
P.O. Box 1014  
Columbia City, IN 46725

Subject: Notification in Accordance with PR Notice 98-10  
**Concrobium**  
EPA Registration Number 82552-1  
Application: November 22, 2005  
Receipt Date: November 25, 2005

Dear Mr. MacDonald:

This will acknowledge receipt of your notification, submitted under the provisions of PR Notice 98-10, FIFRA section 3 (c) 9.

**Proposed Notification:**

- Add minor text to labeling
- Additional Brand Name: Concrobium Mold Control


**General Comment:**

Based on a review of the material submitted, the following comment apply.

The notification application is acceptable. A copy has been inserted in the file for future reference.

Should you have any questions or comments concerning this letter, please contact me at (703) 308-6422 or Renae Whitaker at (703) 308-7003.

Sincerely,

  
Adam Heyward  
Product Manager 34  
Regulatory Management Branch II  
Antimicrobials Division (7510C)

**TASK ASSIGNMENT FORM**  
**Antimicrobial Division/Regulatory Management Branch II**

<b>A</b>	Completed by Product Manager						
PRODUCT REVIEWER <i>Renee Whitaker</i>					RMB <u>II</u> TEAM <u>34</u>		
Description of Action:					EPA File Symbol/Reg No. <i>82552-1</i>		
Decision No. <i>362178</i>		Submission No. <i>1787585</i>		Fee for Service Action Code:			
FQPA Action Code: <i>332</i>		Non-FQPA Action Code:		PRIA FEE AMOUNT:			
		MONTH	DAY	YEAR			
APPLICATION DATE		<i>11</i>	<i>22</i>	2005			
EPA PIN DATE		<i>11</i>	<i>25</i>	2005			
REVIEWER ASSIGNED DATE		<i>12</i>	<i>01</i>	2005			
DATE EXTENDED							
DATE DUE TO PM							
DATE DUE OUT OF AGENCY							
Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure

COMMENTS: *NOTE TO ARCTIC SLOPE - PLEASE COMPLETE PART B OF FORM*

ATTACHMENTS: ☐ LABELING ☐ CSF(S) ☐ DATA ☐ OTHERS

<b>B</b>	For Arctic Slope Contract Only		
Contractor: Arctic Slope		Contract No.: 0411	ARCTIC SLOPE/MANAGER
Draft Task: Signature _____ (Est. hrs)		Final Task: Signature _____ (Total hrs)	

<b>C</b>	Reviewer's Comments:		
DATE FEE PAID:		RESPONSE CODE: <i>17</i>	RESPONSE DATE: <i>12/5/05</i>

## CONCROBIUM

*{Front panel; marketing claims may be used on any panel}*

Encapsulates mold spores (icon)

For Mold Remediation and Prevention (in box)

- Prevents mold and mildew
- Eliminates mold odor
- Contains no ammonia, bleach, alcohol or acid
- Suitable for use on most surfaces
- Fungistat and Mildewstat
- Prevents and inhibits mold and fungi
- Eliminates musty odors
- Contains no ammonia, bleach, alcohol or VOCs
- Odorless and colorless
- Mold Control

### ACTIVE INGREDIENT

Sodium Carbonate.....0.95%

OTHER INGREDIENTS.....99.05%

TOTAL.....100.00%

KEEP OUT OF REACH OF CHILDREN

Directions for Use must be read completely prior to using this product.

Net Contents 25.4 oz./800 ml  
1 quart (946 ml)  
1 gallon /3.8 L  
1 gallon 7 oz. (4 L)  
5 gallon 1 quart 4 oz. (20 L)  
55 gallon (208.175 L)

EPA Reg. No. 82552-1 EPA Est. No. XXXXX-XX-XX

Sold by Siamons International Inc.

Toronto, Canada

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*{Optional marketing claims, may be used on any panel}*

- CONCROBIUM's patented technology encapsulates mold and fungal spores with a microscopic coating that inhibits its growth. Treated surfaces retain a protective barrier that will prevent the growth of mold and mildew.
- For use on most indoor surfaces.

---

Note: Bracketed[ ] information is optional text. Text separated by a comma(,)denotes-and/or-options.  
{Bracketed Text}is for administrative purposes only and will not appear on the printed label.

*{Optional marketing claims, may be used on any panel}*

- Helps prevent mold growth in places vulnerable to mold, including:
  - Basements
  - Bathrooms
  - Vacation homes
  - Boat interiors
  - Areas under construction
- For use in homes, businesses or institutions.
- Contains no volatile organic compounds (VOC's)
- Contains no bleach, ammonia, alcohol or acid
- Odorless and colorless
- No fumes
- Not flammable
- Fungistat
- [Hard Surface] Fungistat
- Mildewstat
- [Hard Surface] Mildewstat
- [Cleans and][Controls][Prevents][Inhibits] the growth of [fungi][mildew][mold][mold and mildew] [and their odors] on [hard surfaces]
- Effective against [fungi][mildew][mold][mold and mildew]
- [Controls][Prevents][Inhibits] [fungi][mildew][mold][mold and mildew]
- Deodorizer
- CONCROBIUM is [specially formulated] [a unique technology] for effective [control] [elimination] of [most] offensive [stains] [odors] caused by mold and mildew.
- Controls [Inhibits] mold and mildew [leaving a fresh clean scent] [leaving rooms clean and fresh smelling].
- Eliminates musty odors [caused by mold and mildew].

---

Note: Bracketed[ ] information is optional text. Text separated by a comma(,) denotes-and/or-options.  
{Bracketed Text} is for administrative purposes only and will not appear on the printed label.



[1G Pro - Back Panel]

Concrobium **dries on surfaces to create an invisible antimicrobial shield** that encapsulates and inhibits the growth of mold and fungal spores, prevents new growth and eliminates musty odors. Concrobium contains no bleach, ammonia, alcohol or other VOCs and is suitable for use on most surfaces.

Use Concrobium to control mold in vulnerable areas such as basements, bathrooms, **closets and around windows**. For use on hard surfaces such as wallboard, **[plaster]**, wood, **metal**, masonry, concrete and **tile**.

**IDEAL FOR**

- >Mold remediation in homes, businesses and institutions
- >Mold prevention following flooding or water damage cleanup
- >Pre-treatment of building materials for mold resistance

**DIRECTIONS FOR USE**

**MOLD AND MILDEW CONTROL IN WOOD, WALLBOARD, CONCRETE AND MASONRY (CINDER) BLOCK CONSTRUCTION MATERIALS IN BUILDINGS**

Concrobium is used to treat wood, wallboard, concrete and masonry (cinder) block building materials to inhibit or prevent the growth of mold organisms when the materials are subjected to moist or wet environments. Before applying this product, visible mold growth must be removed and conditions favorable to mold growth must be identified and corrected.

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

**READ LABEL BEFORE USING**

**PREVENTATIVE TREATMENT**

To inhibit the growth of mold and mildew on surfaces:

- 1) Apply Concrobium on area until evenly wet.
- 2) To promote drying and to avoid residue marks, use a clean cloth or paper towel to wipe off excess wetness.
- 3) Allow treated surfaces to dry completely.

**REMEDIAL TREATMENT**

**SMALL AREAS – TOTAL SURFACE AREA AFFECTED LESS THAN 30 SQUARE FEET**

Areas of visible growth of less than 30 square feet (the area of a single wall panel) can normally be remediated without elaborate procedures. When these areas are identified, apply Concrobium to retard growth and spread of fungal spores and other contaminants until the area can be

thoroughly cleaned and remediated. If growth is on ceiling tiles or other such easily removable items of nominal value, remove them and seal them in a plastic bag and dispose with normal trash. If the surface is not easily replaceable:

- 1) Clean contaminated area to remove surface soil. For best results, and to avoid possible interference from other chemicals, use Concrobium for initial cleaning. Use a cloth, cleaning pad or brush suitable to the durability of the surface being cleaned. Remove as much dirt and visible mold as possible.
- 2) Apply Concrobium on cleaned area until evenly wet.
- 3) To promote drying and to avoid residue marks, use a clean cloth or paper towel to wipe off excess wetness.
- 4) Allow treated surfaces to dry completely.

Refer to the **Personal Protection Equipment Requirements for Applicators** section for the appropriate PPE to wear. [This section along with additional directions for use are contained on [inside][fold out] [other appropriate reference] portion of labeling.]

Concrobium is suitable for use on most surfaces. If in doubt, perform a test on a small, inconspicuous section. Materials vulnerable to water marks should be wiped immediately after contact with Concrobium. Over-application may in some cases result in residue formation, which can be easily wiped away with a Concrobium-dampened cloth.

Concrobium can be applied by hand-spray, paintbrush, roller, immersion, airless sprayer or pressure fogger [(approximately 400 square feet per gallon)] [approximately one gallon of product should treat a 400 sq. ft. room in a fogger)] To maintain protection against re-growth, do not rinse or wash surfaces after treatment. Reapplication of Concrobium may be required if surfaces are washed or painted or are otherwise directly exposed to water.

Ready to use – do not dilute. **Concrobium must come in direct contact with mold to be effective.**

**STORAGE/DISPOSAL:** Do not contaminate water, food or feed by storage or disposal.

**PESTICIDE STORAGE:** Store in original container in areas inaccessible to small children. Keep securely closed.

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:** Triple rinse (or equivalent). Then recycle or recondition, or puncture and dispose of in a sanitary landfill, or incinerate, or if allowed by state and local authorities, burn. If burned, stay out of smoke.

Made in Canada

Questions or Comments? Contact: Customer Service, Siamons International Inc.,  
36 Meteor Drive, Toronto, ON M9W 1A4. 1.866.811.4148 or at [www.concrobium.com](http://www.concrobium.com).

<sup>TM</sup> Concrobium is a trademark of Siamons International Inc. Toronto, Canada

[1G Pro - Inside panel]

## **DIRECTIONS FOR USE (cont.)**

### **REMEDIAL TREATMENT (cont./Large Areas)**

Concrobium is designed to be used to prevent and inhibit the growth of mold, fungus and mildew on floors, walls, interior building surfaces, and other hard non-porous surfaces until such time as the cause of such growth can be identified and corrected. This product should be used in those cases where visible microbial growth has been detected (or conditions are likely to immediately result in such growth) as part of a **comprehensive** program that removes that growth and identifies and corrects the conditions that led to that growth, including:

- Periodic monitoring and inspection of conditions favorable to mold growth such as moisture ingress and high relative humidity
- Effecting repairs as necessary to eliminate conditions favorable to mold growth
- Drying of affected areas to below 20% moisture content

[\*\*][The following associations and Internet sites should be consulted for information on standards and guidelines for remedial treatment of mold and mildew:

- IAQA – Indoor Air Quality Association ([www.iaqa.org](http://www.iaqa.org))
- EPA – Environmental Protection Agency ([www.epa.gov](http://www.epa.gov))
- DOH – New York City Department of Health  
([www.ci.nyc.ny.us/html/doh/html/epi/moldrpt1.html](http://www.ci.nyc.ny.us/html/doh/html/epi/moldrpt1.html))
- IICRC – Institute of Inspection, Cleaning and Restoration Certification ([www.iicrc.org](http://www.iicrc.org))]\*

\*{Either the bulleted statement above or the references in the “Large Areas” to the guidelines are to be included in the labeling}

### **LARGE AREAS – TOTAL SURFACE AREA AFFECTED GREATER THAN 30 SQUARE FEET**

Areas larger than 30 square feet require special procedures and individuals trained in remediation. Guidelines for remediation of large areas of contamination have been established[\*\*.] [by the Indoor Air Quality Associations ([www.iaqa.org](http://www.iaqa.org)) and the US Environmental Protection Agency ([www.epa.gov](http://www.epa.gov)). Many in the field also refer to the New York City Department of Health, “Guidelines on Assessment and Remediation of Fungi in Indoor Environments.”]\* Before using Concrobium in mitigation of large projects, you should be knowledgeable of one or more of these guidelines and follow them when using the product. More information can be obtained from Concrobium’s web site ([www.concrobium.com](http://www.concrobium.com))

When water damage is suspected, the first priority is to find the source of water and cut it off. Once that has been accomplished, excess water should be removed. Detailed guidance on proper removal of excess levels of water is contained in, “Standard and Reference Guide for Professional Water Damage Restoration” (IICRC S500) published by the Institute of Inspection, Cleaning and Restoration Certification [([www.iicrc.org](http://www.iicrc.org))]\*. If excess water has been removed

completely in 24 hours or less, spraying surfaces that were wet with Concrobium will inhibit growth and no other steps should be necessary.

Where structural members and/or contents have been exposed to water in excess of 24 hours, there is a possibility of extensive microbial growth that may be visible or hidden. In that case a complete assessment and remediation plan must be prepared that properly incorporates the use of Concrobium, provides for user and occupant safety and documentation and monitoring of the remediation process. If you are not experienced in preparing and executing such a plan, contact Concrobium Customer Service at (866) 811-4148 for assistance. IICRC S500 contains excellent guidance. In the context of such a plan, Concrobium can be used on materials to be removed and disposed of and in other applications where an anti-microbial use is indicated.

Refer to the [Personal Protection Equipment Requirements for Applicators](#) section for the appropriate PPE to wear.

#### REAPPLICATION

Repeat application weekly or when growth or odor reappears. Prior to reapplication determine the cause of re-growth and correct that problem prior to re-application. Reapplication of Concrobium may be required if surfaces are washed or painted or are otherwise directly exposed to water.

#### PERSONAL PROTECTION EQUIPMENT REQUIREMENTS FOR APPLICATORS

For areas less than 30 sq. feet, an N-95 respirator, gloves and goggles/eye protection are recommended to avoid exposure to mold or mold spores. For areas greater than 30 sq. feet, an N-95 respirator or half-face respirator with HEPA filter, disposable overalls, gloves and goggles/eye protection.



*{Secondary container label for use if contents of 1 gallon label are placed in smaller containers}*

CONCROBIUM  
(Filled by user)

[Secondary Container Label]

Follow directions for use, storage and disposal from the [3.8L] [800 mL] [original]  
[CONCROBIUM] [container] label.

ACTIVE INGREDIENT

Sodium Carbonate... 0.95%

OTHER INGREDIENTS.....99.05%

TOTAL 100.00%

EPA Reg. No. 82552-1

*{Optional marketing claims, may be used on any panel}*

- Helps prevent mold growth in places vulnerable to mold, including:
  - Basements
  - Bathrooms
  - Vacation homes
  - Boat interiors
  - Areas under construction
- For use in homes, businesses or institutions.
- Contains no volatile organic compounds (VOC's)
- Contains no bleach, ammonia, alcohol or acid
- Odorless and colorless
- No fumes
- Not flammable
- Fungistat
- [Hard Surface] Fungistat
- Mildewstat
- [Hard Surface] Mildewstat
- [Cleans and][Controls][Prevents][Inhibits] the growth of [fungi][mildew][mold][mold and mildew] [and their odors] on [hard surfaces]
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- [Controls][Prevents][Inhibits] [fungi][mildew][mold][mold and mildew]
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[1G Pro - Back Panel]

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#### IDEAL FOR

- >Mold remediation in homes, businesses and institutions
- >Mold prevention following flooding or water damage **cleanup**
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#### DIRECTIONS FOR USE

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#### READ LABEL BEFORE USING

#### PREVENTATIVE TREATMENT

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Made in Canada

Questions or Comments? Contact: Customer Service, Siamons International Inc.,  
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[1G Pro - Inside panel]

## **DIRECTIONS FOR USE (cont.)**

### **REMEDIAL TREATMENT (cont./Large Areas)**

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([www.ci.nyc.ny.us/html/doh/html/epi/moldrpt1.html](http://www.ci.nyc.ny.us/html/doh/html/epi/moldrpt1.html))
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When water damage is suspected, the first priority is to find the source of water and cut it off. Once that has been accomplished, excess water should be removed. Detailed guidance on proper removal of excess levels of water is contained in, “Standard and Reference Guide for Professional Water Damage Restoration” (IICRC S500) published by the Institute of Inspection, Cleaning and Restoration Certification [[www.iicrc.org](http://www.iicrc.org))]\*. If excess water has been removed

completely in 24 hours or less, spraying surfaces that were wet with Concrobium will inhibit growth and no other steps should be necessary.

Where structural members and/or contents have been exposed to water in excess of 24 hours, there is a possibility of extensive microbial growth that may be visible or hidden. In that case a complete assessment and remediation plan must be prepared that properly incorporates the use of Concrobium, provides for user and occupant safety and documentation and monitoring of the remediation process. If you are not experienced in preparing and executing such a plan, contact Concrobium Customer Service at (866) 811-4148 for assistance. IICRC S500 contains excellent guidance. In the context of such a plan, Concrobium can be used on materials to be removed and disposed of and in other applications where an anti-microbial use is indicated.

Refer to the [Personal Protection Equipment Requirements for Applicators](#) section for the appropriate PPE to wear.

#### REAPPLICATION

Repeat application weekly or when growth or odor reappears. Prior to reapplication determine the cause of re-growth and correct that problem prior to re-application. Reapplication of Concrobium may be required if surfaces are washed or painted or are otherwise directly exposed to water.

#### PERSONAL PROTECTION EQUIPMENT REQUIREMENTS FOR APPLICATORS

For areas less than 30 sq. feet, an N-95 respirator, gloves and goggles/eye protection are recommended to avoid exposure to mold or mold spores. For areas greater than 30 sq. feet, an N-95 respirator or half-face respirator with HEPA filter, disposable overalls, gloves and goggles/eye protection.

*{Secondary container label for use if contents of 1 gallon label are placed in smaller containers}*

CONCROBIUM  
(Filled by user)

[Secondary Container Label]

Follow directions for use, storage and disposal from the [3.8L] [800 mL] [original]  
[CONCROBIUM] [container] label.

ACTIVE INGREDIENT

Sodium Carbonate... 0.95%

OTHER INGREDIENTS... 99.05%

TOTAL 100.00%

EPA Reg. No. 82552-1



November 22, 2005

Mr. Adam Heyward, PM 34  
Document Processing Desk (NOTIF)  
Office of Pesticide Programs (7504C)  
U. S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1801 South Bell Street  
Arlington, VA 22202-4501

SUBJECT: NOTIFICATION  
Concrobium  
EPA Reg. No.: 82552-1

Dear Adam,

On behalf of our client Siamons International, Inc. ("Siamons") enclosed is a notification for the above mentioned product.

As noted in our e-mailed correspondence to you (11/16/05) we have been working with our client on their labeling and they desire to rearrange certain text and add some minor language to clarify their labeling. In most cases the text proposed is either existing text taken from paragraph form and placed in bullet form or paragraph text pulled together from existing bullets. As you are most likely aware we sometimes have difficulty in certain states when they have to "search" for the text when it is not readily apparent. Therefore to address this situation we are supplying you with this notification for the following text additions in their labeling:

Note: Text that appears to be totally new is highlighted in blue

#### NEW GROUPING OF BULLETS

##### For Mold remediation and Prevention

Mold remediation in homes, businesses and institutions

Pre-treatment of building materials for mold resistance

Concrobium dries on surfaces to create an invisible antimicrobial shield that encapsulates and inhibits the growth of mold and fungal spores, prevents new growth and eliminates musty odors. Concrobium contains no bleach, ammonia, alcohol or other VOC's and is suitable for use on most surfaces.

Use Concrobium to control mold in vulnerable areas such as basements, bathrooms, closets and around windows. For use on hard surfaces such as wallboard, [plaster], wood, metal, masonry, concrete and tile.

Ideal for {followed by previously accepted bullets}



## NEW BULLET

### Mold prevention following flooding or water damage cleanup

#### CORRECTIONS/CLARIFICATIONS

Adam - while the following does not change the directions it clarifies them:

Referral statement - Originally said "Refer to the precautionary statements for the appropriate PPE to wear."

Would like to revise to **"Refer to the Personal Protective Equipment Requirements for Applicators section for appropriate PPE to wear."** also since this section may be on another panel would like to include [This section along with additional directions for use are contained on [inside] [fold out] ["other appropriate reference"] portion of labeling.]

**Materials vulnerable to water marks should be wiped immediately after contact with Concrobium. Over-application may in some cases result in residue formation, which can be easily wiped away with a Concrobium-dampened cloth.**

Alternate language for (approximately 400 square feet per gallon) - [(approximately one gallon of product should treat a 400 sq. ft. room in a fogger)]

**Concrobium must come in direct contact with mold to be effective.**

Add the word "comprehensive" to the statement **"...as part of a comprehensive program that removes the growth and identifies and corrects the conditions that led to the growth."**

#### ADDITIONAL BRAND NAME

##### Concrobium Mold Control

We also wish to notify you of additional package sizes although we understand these may be done by non-notification: 1 quart (946 ml), 1 gallon 7 oz. (4 L), 5 gallon 1 quart 4 oz. (20 L), 55 gallon (208.175 L)

We have attached both a draft of the revised labeling, with the above items highlighted, along with the most recent stamped label. I believe the attached label with its highlights makes the items covered in this notification clearer. We have additionally enclosed a 2<sup>nd</sup> copy of the revised labeling if you can stamp it for pursuing State registrations otherwise we will just provide them a copy of our correspondence to you and your official response to our notification.

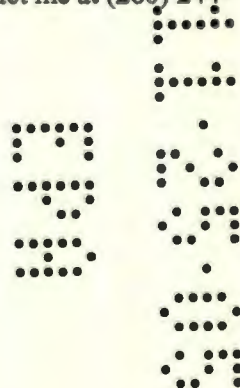
Thank you for your assistance on this matter. If you have any questions please contact me at (260) 244-6270 or by e-mail at [bmacdonald@srcconsultants.com](mailto:bmacdonald@srcconsultants.com).

Sincerely



Bob MacDonald  
Agent for Siamons International, Inc.

cc: E. Green





United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 82552-1	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Concrobium	PM# 34	
5. Name and Address of Applicant (Include ZIP Code) Siamons International, Inc. 36 Meteor Drive Toronto, Ontario Canada M9W 1A4 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

## Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of minor text additions and rearrangement through PR Notice 98-10.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> on label	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input type="checkbox"/> Other _____	

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Bob MacDonald		Title Agent for Siamons International, Inc.	
		Telephone No. (Include Area Code) (260) 244-6270	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			
2. Signature 		3. Title Agent for Siamons International, Inc.	
4. Typed Name Bob MacDonald		5. Date 11/22/05	
6. Date Application Received (Stamped) 			

## CONCROBIUM

*{Front panel; marketing claims may be used on any panel}*

Encapsulates mold spores (icon)

For Mold Remediation and Prevention (in box)

- Prevents mold and mildew
- Eliminates mold odor
- Contains no ammonia, bleach, alcohol or acid
- Suitable for use on most surfaces
- Fungistat and Mildewstat
- Prevents and inhibits mold and fungi
- Eliminates musty odors
- Contains no ammonia, bleach, alcohol or VOCs
- Odorless and colorless
- Mold Control

### ACTIVE INGREDIENT

Sodium Carbonate.....0.95%

OTHER INGREDIENTS.....99.05%

TOTAL.....100.00%

### KEEP OUT OF REACH OF CHILDREN

Directions for Use must be read completely prior to using this product.

Net Contents 25.4 oz./800 ml  
1 quart (946 ml)  
1 gallon /3.8 L  
1 gallon 7 oz. (4 L)  
5 gallon 1 quart 4 oz. (20 L)  
55 gallon (208.175 L)

EPA Reg. No. 82552-1 EPA Est. No. XXXXX-XX-XX

Sold by Siamons International Inc.

Toronto, Canada

*{Optional marketing claims, may be used on any panel}*

- CONCROBIUM's patented technology encapsulates mold and fungal spores with a microscopic coating that inhibits its growth. Treated surfaces retain a protective barrier that will prevent the growth of mold and mildew.
- For use on most indoor surfaces.

Note: Bracketed[ ] information is optional text. Text separated by a comma(,) denotes-and/or-options.  
{Bracketed Text} is for administrative purposes only and will not appear on the printed label.



**TASK ASSIGNMENT FORM**  
**Antimicrobial Division/Regulatory Management Branch II**

<b>A</b>	Completed by Product Manager						
PRODUCT REVIEWER <b>LISA MCKELVIN</b>						RMB <u>II</u> TEAM <u>34</u>	
Description of Action:						EPA File Symbol/Reg No. <b>82552-R</b>	
Decision No. <u>357584</u>			Submission No. <u>779613</u>		Fee for Service Action Code: <b>A54</b>		
FQPA Action Code: <del>8</del>		Non-FQPA Action Code:			PRIA FEE AMOUNT: <b>\$4,000.00</b>		
		MONTH	DAY	YEAR			
APPLICATION DATE		MAY	27	2005			
EPA PIN DATE		MAY	31	2005			
REVIEWER ASSIGNED DATE		June	13	2005			
DATE DUE FROM SCIENCE		<b>AUGUST</b>	<b>29</b>	<b>2005</b>			
DATE DUE TO PM		<b>SEPTEMBER</b>	<b>06</b>				
DATE DUE OUT OF AGENCY		<b>SEPTEMBER</b>	<b>28</b>				
Type of Data:	PSB Product Chemistry ✓	PSB Acute Toxicology ✓	PSB Efficacy ✓	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure
COMMENTS: <b>NOTE TO ARCTIC SLOPE - PLEASE COMPLETE PART B OF FORM</b>							
ATTACHMENTS: <input type="checkbox"/> -LABELING <input type="checkbox"/> -CSF(S) <input type="checkbox"/> -DATA <input type="checkbox"/> -OTHERS							
<b>B</b>	For Arctic Slope Contract Only						
Contractor: Arctic Slope				Contract No.: 0332		ARCTIC SLOPE/MANAGER	
Draft Task: Signature _____ (Est. hrs)				Final Task: Signature _____ (Total hrs)			
<b>C</b>	Reviewer's Comments:						
DATE FEE PAID:				RESPONSE CODE: <u>18</u> RESPONSE DATE: <u>10/13/05</u>			





U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Antimicrobials Division (7510C)  
1200 Pennsylvania Avenue NW  
Washington, D.C. 20460

EPA Reg.  
Number:  
82552-1

Date of Issuance:  
October 13, 2005

Term of Issuance:

**Conditional**

Name of Pesticide Product:

**Concrobium**

NOTICE OF PESTICIDE:

  x   Registration  
      Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Siamons International, Inc.  
36 Meteor Drive  
Toronto, Ontario Canada M9W 1A4

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

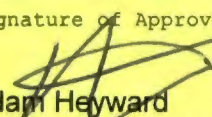
This product is conditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for shipment:

a. Add the phrase "EPA Registration Number "82552-1".

Signature of Approving Official:

  
Adam Hayward  
Product Manager Team-34  
Regulatory Management Branch II  
Antimicrobials Division (7510C)

Date:

October 13, 2005

- b. Revise the statement "Will not damage most surfaces" to read "Suitable for use on most surfaces" on the front panel and page no. 3 of the labeling.
- c. Add the following statement immediately below the directions for uses statement.

**MOLD AND MILDEW CONTROL IN WOOD, WALLBOARD, CONCRETE, AND MASONRY (CINDER) BLOCK CONSTRUCTION MATERIALS IN BUILDINGS**

CONCROBIUM is used to treat wood, wall board, concrete, and masonry (cinder) block building materials to inhibit or prevent the growth of mold organisms when the materials are subjected to moist or wet environments. Before applying this product, visible mold growth must be removed, and conditions favorable to mold growth must be identified and corrected.

3. Submit the following data for the active ingredient "sodium carbonate" within the time specified below.

- a) Preliminary analysis data: Product Chemistry Series Guideline No. 830.1700 by January 30, 2006.
- b) One-year storage stability data (830.6317) and corrosion characteristics data by March 1, 2007.

Note: Good Laboratory Practices are required for preliminary analysis and storage stability/corrosion characteristics studies.

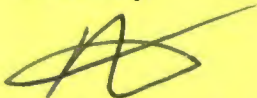
4. Submit a certificate of analysis for the active ingredient sodium carbonate.

Submit three (3) copies of the final printed label prior to releasing this product for sale.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,



Adam Heyward  
Product Manager 34  
Regulatory Branch II  
Antimicrobials Division (7510C)

## CONCROBIUM

*{Front panel; marketing claims may be used on any panel}*

- Prevents mold and mildew
- Eliminates mold odor
- Contains no ammonia, bleach, alcohol or acid
- Will not damage most surfaces
- Fungistat and Mildewstat

### ACTIVE INGREDIENT

Sodium Carbonate... 0.95%

OTHER INGREDIENTS... 99.05%

TOTAL 100.00%

Keep Out of Reach of Children

Net Contents 25.4 oz./800 mL  
1 Gallon/3.8 L

EPA Reg. No. 82552-R  
EPA Est. No. XXX-CN-01

Directions for Use must be read completely prior to using this product.

Siamons International Inc.  
Toronto, ON M9W 1A4

ACCEPTED  
with COMMENTS  
EPA Letter Dated:

OCT 13 2005

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act as  
amended, for the pesticide,  
registered under EPA Reg. No. 82552-R-1

*{Optional marketing claims, may be used on any panel}*

- CONCROBIUM's patented technology encapsulates mold and fungal spores with a microscopic coating that inhibits its growth. Treated surfaces retain a protective barrier that will prevent the growth of mold and mildew.
- For use on most indoor surfaces.
- Helps prevent mold growth in places vulnerable to mold, including:
  - Basements
  - Bathrooms
  - Vacation homes
  - Boat interiors
  - Areas under construction
- For use in homes, businesses or institutions.
- Contains no volatile organic compounds (VOC's)
- Contains no bleach, ammonia, alcohol or acid
- Odorless and colorless
- No fumes
- Not flammable
- Fungistat
- [Hard Surface] Fungistat
- Mildewstat
- [Hard Surface] Mildewstat
- [Cleans and][Controls][Prevents][Inhibits] the growth of [fungi][mildew][mold][mold and mildew] [and their odors] on [hard surfaces]
- Effective against [fungi][mildew][mold][mold and mildew]
- [Controls][Prevents][Inhibits] [fungi][mildew][mold][mold and mildew]
- Deodorizer
- CONCROBIUM is [specially formulated] [a unique technology] for effective [control] [elimination] of [most] offensive [stains] [odors] caused by mold and mildew.

---

Note: Bracketed [ ] information is optional text. Text separated by a comma(,) denotes--and/or-options.  
{Bracketed Text} is for administrative purposes only and will not appear on the printed label.



- Controls [Inhibits] mold and mildew [leaving a fresh clean scent] [leaving rooms clean and fresh smelling].
- Eliminates musty odors [caused by mold and mildew].

### **Directions for Use:**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

### **READ LABEL BEFORE USING**

CONCROBIUM will not harm most surfaces. If in doubt, first perform a test application on a small, inconspicuous section of the surface in question. Do not use on surfaces vulnerable to water marks (such as leather or finished wood). If product contacts these surfaces, it should be wiped off immediately to prevent damage.

CONCROBIUM is designed to be used to prevent and inhibit the growth of mold, fungus and mildew on floors, walls, interior building surfaces, and other hard non-porous surfaces until such time as the cause of such growth can be identified and corrected. This product should be used in those cases where visible microbial growth has been detected (or conditions are likely to immediately result in such growth) as part of a program that removes that growth and identifies and corrects the conditions that led to that growth. As well, this product can be used to pre-treat building materials prior to being employed in a structure where an increase in the mold and fungus resistance of these materials would be desirable.

CONCROBIUM can be applied by hand-spray, paintbrush, roller, immersion, airless sprayer or pressure fogger (approximately 400 square feet per gallon). To maintain protection against re-growth, do not rinse or wash surfaces after treatment. Reapplication of CONCROBIUM may be required if surfaces are washed or painted or are otherwise directly exposed to water.

Ready to use—do not dilute.

### **PREVENTATIVE TREATMENT**

To inhibit the growth of mold and mildew on surfaces:

- 1) Apply CONCROBIUM on area until evenly wet.
- 2) To promote drying and to avoid residue marks, use a clean cloth or paper towel to wipe off excess wetness.
- 3) Allow treated surfaces to dry completely.

## REMEDIAL TREATMENT

CONCROBIUM must be used as part of a comprehensive mold remediation or water damage restoration program, including:

- Periodic monitoring and inspection of conditions favorable to mold growth such as moisture ingress and high relative humidity
- Effecting repairs as necessary to eliminate conditions favorable to mold growth
- Drying of affected areas to below 20% moisture content

The following associations and Internet sites should be consulted for information on standards and guidelines for remedial treatment of mold and mildew:

- IAQA – Indoor Air Quality Association ([www.iaqa.org](http://www.iaqa.org))
- EPA – Environmental Protection Agency ([www.epa.gov](http://www.epa.gov))
- DOH – New York City Department of Health  
([www.ci.nyc.ny.us/html/doh/html/epi/moldrpt1.html](http://www.ci.nyc.ny.us/html/doh/html/epi/moldrpt1.html))
- IICRC – Institute of Inspection, Cleaning and Restoration Certification  
([www.iicrc.org](http://www.iicrc.org))

### Small Areas – Total Surface Area Affected Less Than 30 Square Feet

Areas of visible growth of less than 30 square feet (the area of a single wall panel) can normally be remediated without elaborate procedures. When these areas are identified, apply CONCROBIUM to retard growth and spread of fungal spores and other contaminants until the area can be thoroughly cleaned and remediated. If growth is on ceiling tiles or other such easily removable items of nominal value, remove them and seal them in a plastic bag and dispose with normal trash. If the surface is not easily replaceable:

- 1) Clean contaminated area to remove surface soil. For best results, and to avoid possible interference from other chemicals, use CONCROBIUM for initial cleaning. Use a cloth, cleaning pad or brush suitable to the durability of the surface being cleaned. Remove as much dirt and visible mold as possible.
- 2) Apply CONCROBIUM on cleaned area until evenly wet.
- 3) To promote drying and to avoid residue marks, use a clean cloth or paper towel to wipe off excess wetness.
- 4) Allow treated surfaces to dry completely.

Refer to the precautionary statements for the appropriate PPE to wear.

## **Large Areas – Total Surface Area Affected Greater Than 30 Square Feet**

Areas larger than 30 square feet require special procedures and individuals trained in remediation. Guidelines for remediation of large areas of contamination have been established by the Indoor Air Quality Associations ([www.iaqa.org](http://www.iaqa.org)) and the US Environmental Protection Agency ([www.epa.gov](http://www.epa.gov)). Many in the field also refer to the New York City Department of Health, "Guidelines on Assessment and Remediation of Fungi in Indoor Environments." Before using CONCROBIUM in mitigation of large projects, you should be knowledgeable of one or more of these guidelines and follow them when using the product. More information can be obtained from CONCROBIUM's web site ([www.concrobium.com](http://www.concrobium.com))

When water damage is suspected, the first priority is to find the source of water and cut it off. Once that has been accomplished, excess water should be removed. Detailed guidance on proper removal of excess levels of water is contained in, "Standard and Reference Guide for Professional Water Damage Restoration" (IICRC S500) published by the Institute of Inspection, Cleaning and Restoration Certification ([www.iicrc.org](http://www.iicrc.org)). If excess water has been removed completely in 24 hours or less, spraying surfaces that were wet with CONCROBIUM will inhibit growth and no other steps should be necessary.

Where structural members and/or contents have been exposed to water in excess of 24 hours, there is a possibility of extensive microbial growth that may be visible or hidden. In that case a complete assessment and remediation plan must be prepared that properly incorporates the use of CONCROBIUM, provides for user and occupant safety and documentation and monitoring of the remediation process. If you are not experienced in preparing and executing such a plan, contact CONCROBIUM Customer Service at (866) 811-4148 for assistance. IICRC S500 contains excellent guidance. In the context of such a plan, CONCROBIUM can be used on materials to be removed and disposed of and in other applications where an anti-microbial use is indicated.

Refer to the precautionary statements for the appropriate PPE to wear.

### **Personal Protection Equipment Requirements for Applicators**

For areas less than 30 sq. feet, an N-95 respirator, gloves and goggles/eye protection are recommended to avoid exposure to mold or mold spores. For areas greater than 30 sq. feet, an N-95 respirator or half-face respirator with HEPA filter, disposable overalls, gloves and goggles/eye protection.

### **Reapplication**

Repeat application weekly or when growth or odor reappears. Prior to reapplication determine the cause of re-growth and correct that problem prior to re-application. Reapplication of Concrobium may be required if surfaces are washed or painted or are otherwise directly exposed to water.

**STORAGE/DISPOSAL:** Do not contaminate water, food or feed by storage or disposal.

**PESTICIDE STORAGE:** Store in original container in areas inaccessible to small children. Keep securely closed.

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:** Triple rinse (or equivalent). Then recycle or recondition, or puncture and dispose of in a sanitary landfill, or incinerate, or if allowed by state and local authorities, burn. If burned, stay out of smoke.

Lot No. XXXXXXXX

- Made in Canada
- Questions or Comments? Write:  
Customer Service,  
Siamons International Inc.,  
36 Meteor Road,  
Toronto, ON M9W 1A4

Visit our web site at [www.xxxxxxxxxx.com](http://www.xxxxxxxxxx.com)



*{Secondary container label for use if contents of 1 gallon label are placed in smaller containers}*

CONCROBIUM  
(Filled by user)

[Secondary Container Label]

Follow directions for use, storage and disposal from the [3.8L] [800 mL] [original]  
[CONCROBIUM] [container] label.

ACTIVE INGREDIENT

Sodium Carbonate... 0.95%

OTHER INGREDIENTS... 99.05%

TOTAL 100.00%

EPA Reg. No. 82552-R



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

August 23, 2005

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 82552-R  
DP Barcode: D318257  
Case No:

To: Adam Heyward PM 34 / Lisa McKelvin, Team Reviewer  
Regulatory Management Branch  
Antimicrobials Division (7510C)

From: Robert A. Turpin, Jr., Scientist *R. T.*  
Chemistry/Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510C)

*[Handwritten signature]*  
*8/23/05*

Michele E. Wingfield, Chief  
Product Science Branch  
Antimicrobials Division (7510C)

Applicant: Siamons International, Inc.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Trisodium phosphate .....	1.19
<u>Other Ingredient(s):</u> .....	<u>98.81</u>
Total:	100%

BACKGROUND: The applicant has submitted an application for registration of its product, Concrobium. In support of the application, the applicant has submitted test reports responding to the requirements of OPPTS Test Guidelines for acute toxicity studies, 870.1100, -1200, -1300, -2400, -2500, and -2600.

RECOMMENDATIONS (PSB findings):

The acute toxicity profile for Reg. No. 82552-R is currently:

acute oral toxicity	IV	Acceptable
acute dermal toxicity	IV	Acceptable
acute inhalation toxicity	IV	Acceptable
primary eye irritation	IV	Acceptable
primary skin irritation	IV	Acceptable
dermal sensitization	Non-sensitizer	Acceptable

LABELING:

Date: August 23, 2005

ID #: 82552-R

Signal Word: [Not required]

First Aid Statement: [Not required]

# DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§ 81-1, 870.1100)

**Product Manager:** Adam Heyward  
**MRID No.:** 465589-04

**Reviewer:** Robert Turpin  
**Study Completion Date:** 11/17/04  
**Report No.:** 8489-04

**Testing Laboratory :** Stillmeadow, Inc.  
**Authors :** Janice O. Kuhn

**Quality Assurance (40 CFR §160.12):** Statement provided.

**Test Material:** Siamons Mold Control

**Species:** Rat  
**Age:** Young adults  
**Weight:** 177-181 g  
**Source:** Texas Animal Specialties

## Conclusion:

1. LD<sub>50</sub> (mg/kg):                      Males = NA  
   Females = >5,000  
   Combined = NA
2. The estimated LD<sub>50</sub> is >5,000 mg/kg
3. Tox. Category: IV                      Classification: Acceptable

**Procedure (Deviations from §81-1):** None stated.

## Results:

Dosage (mg/kg)	(Number Deaths/Number Tested)		
	Males	Females	Combined
5,000	NA	0/3	0/3

**Observations:** Each of the animals gained weight. No signs of toxic effect were noted.

**Gross Necropsy:** No gross abnormalities were noted.



## DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2, 870.1200)

**Product Manager:** Adam Heyward  
**MRID No.:** 465589-05

**Reviewer:** Robert Turpin  
**Study Completion Date:** 11/18/04  
**Report No.:** 8490-04

**Testing Laboratory:** Stillmeadow, Inc.

**Author:** Janice O. Kuhn

**Quality Assurance (40 CFR §160.12):** Statement provided.

**Test Material:** Siamons Mold Control

**Species:** Rabbit

**Weight:** Males: 2.000-2.450 kg; Females: 2.100-2.450 kg.

**Age:** ~12 weeks

**Source:** Nicols Rabbitry Inc.

### Summary:

1. **LD<sub>50</sub> (mg/kg):**                      **Males** = > 5050 mg/kg  
   **Females** = > 5050 mg/kg  
   **Combined** = >5050 mg/kg

2. **The estimated LD<sub>50</sub> is** >5050 mg/kg

3. **Tox. Category:** IV                      **Classification:** Acceptable

**Procedure (Deviation From §81-2):** None noted.

### Results:

#### Reported Mortality

DOSAGE (mg/kg)	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
5050	0/5	0/5	0/10

**Observations:** There was no mortality during the study. All animals appeared normal for the duration of the test. All animals gained weight.

**Gross Necropsy Findings:** There were no observable abnormalities upon necropsy.

## DATA REVIEW FOR ACUTE INHALATION TOXICITY (§81-3, 870.1300)

**Product Manager:** Adam Heyward  
**MRID No.:** 465589-06

**Reviewer:** Robert Turpin  
**Study Completion Date:** 12/21/04  
**Report No.:** 8491-04

**Testing Laboratory:** Stillmeadow, Inc.

**Author:** Lori Carter

**Quality Assurance (40 CFR §160.12):** Statement provided.

**Test Material:** Siamons Mold Control

**Concentration:** 2.28 mg/L

**Species:** Rat

**Weight:** Males: 262-317 g; Females 195-210 g

**Age:** ~ 8 weeks

**Source:** Texas Animal Specialties

### Summary:

1. **LC<sub>50</sub> (mg/L):** Males = > 2.28

Females = >2.28

Combined = >2.28

2. **The estimated LC<sub>50</sub> is** >2.28 mg/L

3. **MMAD:** 2.9 µm

4. **Tox. Category:** IV

**Classification:** Acceptable

**Procedure (Deviation From §81-3):** None stated.

### Results:

#### Reported Mortality

Exposure Concentration	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
2.28 mg/L	0/5	0/5	0/10

Chamber Atmosphere			
Dose Level	MMAD	GSD	particles <
2.28 mg/L	2.9 µm	3.8 µm	16
	µm	µm	

Chamber Environment	
Chamber Volume	500 L
Airflow	195 Lpm
Temperature	65 ° F
Relative Humidity	67%

**Clinical Observations:** Male and female animals exhibited piloerection and decreased activity through day one after which showed no signs of abnormalities through end of test and observation period.

**Gross Necropsy Findings:** No abnormalities observed.

# DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

**Product Manager:** Adam Heyward  
**MRID No.:** 465589-07

**Reviewer:** Robert Turpin  
**Study Completion Date:** 11/17/04  
**Report No.:** 8492-04

**Testing Laboratory:** Stillmeadow, Inc.  
**Author(s):** Janice O. Kuhn

**Quality Assurance (40 CFR §160.12):** Statement provided.

**Test Material:** Siamons Mold Control

**Dosage:** 0.1 ml

**Species:** Rabbit

**Sex:** 2 males, 1 female

**Weight:** Males: 2.300-2.650 kg; Female: 2.400 kg

**Age:** ~ 12 weeks

**Source:** Nicols Rabbitry Inc.

## Summary:

1. **Toxicity Category:** IV

2. **Classification:** Acceptable

**Procedure (Deviations From §81-4):** None noted.

## Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Corneal Opacity	0/3	0/3	0/3	0/3	---	---	---	---
Iritis	0/3	0/3	0/3	0/3	---	---	---	---
Conjunctivae								
Redness	0/3	0/3	0/3	0/3	---	---	---	---
Chemosis	0/3	0/3	0/3	0/3	---	---	---	---
Discharge	0/3	0/3	0/3	0/3	---	---	---	---

--- = no observations at this point



## **DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6, 870.2600)**

**Product Manager:** Adam Heyward  
**MRID No.:** 465589-09

**Reviewer:** Robert Turpin  
**Study Completion Date:** 12/1/04  
**Report No.:** 8494-04

**Testing Laboratory:** Stillmeadow, Inc.  
**Author:** Janice O. Kuhn

**Quality Assurance (40 CFR §160.12):** Statement provided.

**Test Material:** Siamons Mold Control

**Positive Control Material:** alpha-hexylcinnamaldehyde:olive oil

**Species:** Mouse

**Weight:** 20.5-28.5 g

**Age:** ~ 10 weeks

**Source:** Harlan Sprague-Dawley

**Method:** Local Lymph Node Assay

### **Summary:**

**1. This Product is not a dermal sensitizer.**

**2. Classification:** Acceptable

**Procedure (Deviation From §81-6):** None noted.

**Procedure:** Five female mice were selected for each of three test Groups. On days 1, 2, and 3 the animals in each of the groups received a 25 µl dose of an appropriate dilution (25% or 50%) of the test substance, or the undiluted test substance, to the dorsum of both ears. Control animals were treated in the same way with the vehicle, only. Following a 2 day rest period the test and control animals were injected in the tail with 250 µl of 0.01 M phosphate-buffered saline containing 20 µCi of [methyl, 1<sup>1</sup>, 2<sup>1-3</sup>H] Thymidine. Five hours after the injection, the animals were sacrificed, the draining auricular lymph nodes were excised and pairs from each animal were processed.

**Results:** The product produced a stimulation index of <3 in all groups of test animals, and is not considered a sensitizer.

## ACUTE TOX ONE-LINER

1. PC CODE: 076406
2. CURRENT DATE: 8/23/05
3. TEST MATERIAL: Trisodium phosphate (Concrobium)

Study/Species/Lab/ Study#/Date	MRID No.	Results	Tox. Cat.	Core Grade
acute oral toxicity /Rat/ Stillmeadow/ 8489-04/ 11-17- 04	465589-04	LD <sub>50</sub> (mg/kg) = >5,000	IV	A
acute dermal toxicity /Rabbit/ Stillmeadow/ 8490-04/ 11-18- 04	465589-05	LD <sub>50</sub> (mg/kg) = >5050	IV	A
acute inhalation toxicity / Rat/ Stillmeadow/ 8491-04/ 12-21- 04	465589-06	LC <sub>50</sub> (mg/L) = 2.28	IV	A
primary eye irritation /Rabbit/ Stillmeadow/ 8492-04/ 11-17- 04	465589-07	Not an irritant	IV	A
primary skin irritation / Rabbit/ Stillmeadow/ 8493-04/ 11-1-04	465589-08	Not an irritant	IV	A
dermal sensitization / Mouse/ Stillmeadow/ 8494-04	465589-09	Non-sensitizer	---	A

A = Acceptable  
 U = Unacceptable  
 S = Supplementary  
 V = self-Validated

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Washington, D.C. 20460



OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES  
Antimicrobial Division

10/13/05

**SUBJECT:** PRODUCT CHEMISTRY REVIEW OF: **CONCROBIUM**

**DP Barcode:** D318256 (update)

**Reg. No. or File Symbol** 82552-R

**TGAI/Manufacturing-use Product** ☐ **OR** **End-use Product** ☒

**TO:** Adam Heyward / Lisa McKelvin  
PM Team 34

**FROM:** Juan F. Negrón, Chemist / *JFN*  
Product Science Branch, CT Team  
Antimicrobial Division (7510C)

**THRU:** Karen P. Hicks, CT Team Leader  
Product Science Branch  
Antimicrobial Division (7510C)

**THRU:** Michele E. Wingfield, Chief  
Product Science Branch  
Antimicrobial Division (7510C)

**APPLICANT:** Siamons International, Inc.

**Action code:**

**Due date:**

**Product Formulation**  
**Active Ingredient(s)**

Sodium carbonate

% by wt.  
0.95

*Kw P. Hicks*  
*10/13/05*

## BACKGROUND:

The registrant, Siamons International, Inc., is submitting a new registration data package for review. The non-integrated end-use product, **CONCROBIUM**, prevents mold & mildew, eliminates mold odor, and is a fungi-stat and mildew-stat. The registrant changes the active ingredient (AI) from trisodium phosphate to sodium carbonate.

## FINDINGS:

1. The Product Chemistry Reviewer has received the following documents:
  - Confidential Statement of Formula (CSF), dated 10/06/05, for the basic formulation.
  - A letter, dated 10/06/05.
  - A label, dated 10/06/05.
  - Application for pesticide, dated 10/07/05, EPA Form 8570-1.
  - Certification with respect to citation of data, dated 10/06/05, EPA Form 8570-34.
  - Data matrix, dated 10/06/05, EPA Form 8570-35.
2. The CSF, dated 10/06/05, for the basic formulation is revised.
3. The CSF and the label have the same nominal.
4. The registrant changes the AI from trisodium phosphate to sodium carbonate.
5. The product is an unregistered source.
6. No five batches had been submitted.
7. No certificate of analysis for sodium carbonate has been submitted.
8. The registrant changes the AI on the label from trisodium phosphate to sodium carbonate.



**RECOMMENDATIONS:**

1. The registrant needs to submit a certificate of analysis for sodium carbonate.
2. The registrant needs to perform the one-year storage stability study along with the corrosion characteristics study.
3. The registrant needs to submit the 830.1700 preliminary analysis for sodium carbonate as AI.
4. The previous Product Chemistry Review should be considering harmonizing with the new proposal.

**CONCLUSION:**

The CSF, dated 10/06/05, for the basic formulation is acceptable. The CSF and the label have the same nominal. The registrant needs to submit 830.1700 Preliminary Analysis once they start the full-scale production. The registrant must comply with the requirements, recommendations and concerns listed above.

**SRC**  
**Scientific & Regulatory**  
Consultants, Inc.

October 6, 2005

Mr. Adam Heyward, PM 34  
Document Processing Desk (APPL)  
Office of Pesticide Programs (7504C)  
U. S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1801 South Bell Street  
Arlington, VA 22202

SUBJECT: Concrobium  
EPA Reg. No.: 82552-R

Dear Adam,

On behalf of our client Siamons International, Inc. ("Siamons") enclosed are revised administrative materials to support the pending registration for Concrobium. This information is supplied based on agreements reached between Mr. Mark Hartman, EPA, and Mr. Eric Green, Siamons, regarding the declaration of the unregistered active sodium carbonate as the active ingredient.

Concrobium is designed to be used to prevent and inhibit the growth of mold, fungus and mildew on floors, walls, and other hard non-porous interior building surfaces until such time as the cause of such growth can be identified and corrected. Such claims have traditionally been considered non-public health claims by the EPA. This was confirmed by the efficacy staff during the review process for Concrobium.

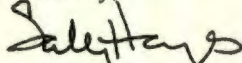
As suggested by the Agency, we used two currently registered labels as guidance for preparing the Concrobium label. These labels used as models were BBJ Microbicide, EPA Reg. 67212-1 and Clortram F-40, EPA Reg. No. 72304-1.

To support this registration we are submitting:

1. Confidential Statement of Formula
2. Certification with Respect to Citation of Data for sodium carbonate
3. Data Matrix for sodium carbonate
4. Label (5 copies)

You can contact me at (260) 244-6270 or shayes@srcconsultants.com if you need clarification or have any questions about this registration.

Sincerely,



Sally Hayes  
Agent for Siamons International, Inc.

cc: E. Green



United States  
Environmental Protection Agency  
Washington, DC 20460

☒ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 82552-R	2. EPA Product Manager Adam Heyward	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Concrobium	PM # 34	
5. Name and Address of Applicant (Include ZIP Code) Siamons International, Inc. 36 Meteor Drive Toronto, Ontario Canada M9W 1A4 <input type="checkbox"/> Check if this is a new address	6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

Submitted in response to phone call from Adam Heyward on October 6, 2005. This is additional information for a pending submission and is not a PRIA action.

## Section - III

1. Material This Product Will Be Packaged In:						2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No				<input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* <b>Certification must be submitted</b>		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 4 liter, 750 mL		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label accompanying product			
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

## Section - IV

1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Sally Hayes	Title Agent for Siamons International, Inc.	Telephone No. (include Area Code) 260-244-6270
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped) 
2. Signature 	3. Title Agent for Siamons International, Inc.	
5. Typed Name Sally Hayes	5. Date October 7, 2005	



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

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 Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Siamons International, Inc. 36 Meteor Drive Toronto, Ontario M9W 1A4 Canada 416-674-9500	EPA Registration Number/File Symbol 82552- <del>X</del> 1
Active Ingredient(s) and/or representative test compound(s) Sodium Carbonate (CAS 497-19-8)	Date 10/06/05
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Prevent/ inhibit mold, fungus, mildew on hard non-porous surfaces	Product Name Concrobium

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulators Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

☒ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☐ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method, or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Sally Hayes</i>	Date 10/06/05	Typed or Printed Name and Title Sally Hayes, Agent for Siamons International, Inc.
---------------------------------	------------------	---



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## DATA MATRIX

Date	October 6, 2005	EPA Reg No./File Symbol	82552-R	Page 1 of 1	
Applicant's/Registrant's Name & Address Siamons International, Inc., 36 Meteor Drive, Toronto, Ontario, M9W 1A4, Canada		Product Concrobium			
Ingredient Sodium Carbonate (CAS 497-19-8)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
All required for this use pattern	Cite-All	NA	See attached list	Pay	
Signature Sally Hayes			Name and Title Sally Hayes, Agent for Siamons International, Inc.	Date October 6, 2005	

**Applicant's/Registrant's Name & Address**

Siamons International, Inc., 36 Meteor Drive, Toronto, Ontario, M9W 1A4, Canada

Product

## Concrobium

**Ingredient** Sodium Carbonate (CAS 497-19-8)

[illegible]

Signature Sally Hays

Name and Title

Sally Hayes, Agent for Siamons International, Inc.

Date \_\_\_\_\_

October 6, 2005

XX XX

COMPANY# 072563 AMERICAN BIOPHYSICS CORP.  
\* DATA TYPES \* 140 FRENCHTOWN ROAD  
EU AT EC FW EF OT NORTH KINGSTOWN, RI 02852  
XX XX

CHEMICAL CHEMICAL NAME  
073502 Calcium carbonate

COMPANY# 066607 SPRAY DRIFT TASK FORCE  
\* DATA TYPES \* 1900 K STREET, NW  
EU AT EC FW EF OT WASHINGTON, DC 20006  
XX

CHEMICAL CHEMICAL NAME  
073504 Potassium carbonate

COMPANY# 005813 CLOROX CO., THE  
\* DATA TYPES \* C/O PS&RC  
EU AT EC FW EF OT PO BOX 493  
XX XX PLEASANTON, CA 94566

CHEMICAL CHEMICAL NAME  
073505 Sodium bicarbonate

COMPANY# 000464 DOW CHEMICAL CO., THE  
\* DATA TYPES \* ATTN: RHONDA VANCE-MOESER  
EU AT EC FW EF OT 1803 BUILDING  
XX MIDLAND, MI 48674

COMPANY# 066607 SPRAY DRIFT TASK FORCE  
\* DATA TYPES \* 1900 K STREET, NW  
EU AT EC FW EF OT WASHINGTON, DC 20006  
XX

CHEMICAL CHEMICAL NAME  
073506 Sodium carbonate

COMPANY# 000077 SOLVIT CHEMICAL COMPANY INC  
\* DATA TYPES \* 7001 RAYWOOD ROAD  
EU AT EC FW EF OT MADISON, WI 53713  
XX XX XX XX XX

COMPANY# 000527 ROCHESTER MIDLAND  
\* DATA TYPES \* 333 HOLLENBECK STREET  
EU AT EC FW EF OT ROCHESTER, NY 14603  
XX XX

COMPANY# 000733 ALLIED KELITE PRODUCTS DIVISION  
\* DATA TYPES \* 1250 NORTH MAIN  
EU AT EC FW EF OT LOS ANGELES, CA 90012

XX

COMPANY# 000984 WHITMOYER LAB INC  
\* DATA TYPES \* 19 NORTH RAILROAD ST.  
EU AT EC FW EF OT MYERSTOWN, PA 17067  
XX

COMPANY# 001020 OAKITE PRODUCTS INC  
\* DATA TYPES \* 50 VALLEY RD  
EU AT EC FW EF OT BERKELEY HEIGHTS, NJ 07922  
XX XX

COMPANY# 001190 J.F. DALEY INTERNATIONAL, LTD.  
\* DATA TYPES \* PECK'S PRODUCTS DIVISION  
EU AT EC FW EF OT 1200 SWITZER AVE  
XX ST. LOUIS, MO 63147

COMPANY# 001325 M.S.I.  
\* DATA TYPES \* 2010 CENTURY CTR BLVD, SUITE 1  
EU AT EC FW EF OT IRVING, TX 75062

XX

COMPANY# 001385 WICH-CRAFT INSTITUTIONAL MAINTENANCE SUPPLY  
\* DATA TYPES \* 1040 SO SANTA FE  
EU AT EC FW EF OT WICHITA, KS 67211  
XX XX XX XX XX

COMPANY# 001430 CAMP CHEMICAL COMPANY INC  
\* DATA TYPES \* 136 VERDI STREET  
EU AT EC FW EF OT FARMINGDALE, NY 11735  
XX XX

COMPANY# 001762 ASSOC CHEMISTS INC  
\* DATA TYPES \* 4401 SE JOHNSON CK BLVD  
EU AT EC FW EF OT PORTLAND, OR 97222  
XX

COMPANY# 003573 THE PROCTER & GAMBLE COMPANY  
\* DATA TYPES \* 5299 SPRING GROVE AVE - F&HC PS&RA  
EU AT EC FW EF OT CINCINNATI, OH 45217  
XX XX XX

COMPANY# 003635 JOHNSON DIVERSEY, INC.  
\* DATA TYPES \* Agent for: DIVERSEY LEVER  
EU AT EC FW EF OT 8310 16TH STREET  
XX STURTEVANT, WI 53177

COMPANY# 004169 ABORN CHEMICAL INDUSTRIES INC  
\* DATA TYPES \* 92 YORK AVE  
EU AT EC FW EF OT RANDOLPH, MA 02368  
XX

COMPANY# 004591 LYNDE CO  
\* DATA TYPES \* 3040 EAST HENNEPIN AVE  
EU AT EC FW EF OT MINNEAPOLIS, MN 55413  
XX

COMPANY# 004829 COASTAL INDUSTRIES  
\* DATA TYPES \* 225 PASSAIC STREET  
EU AT EC FW EF OT PASSAIC, NJ 07055  
XX

COMPANY# 005813 CLOROX CO., THE  
\* DATA TYPES \* C/O PS&RC  
EU AT EC FW EF OT PO BOX 493  
XX PLEASANTON, CA 94566

COMPANY# 006142 H KOHNSTAMM & COMPANY INC  
\* DATA TYPES \* 165 N. CANAL STREET SUITE 975  
EU AT EC FW EF OT CHICAGO, IL 60606  
XX

COMPANY# 006185 EMARKAY LABS  
\* DATA TYPES \* PO BOX 531  
EU AT EC FW EF OT VINELAND, NJ 08360  
XX

COMPANY# 006418 MAGEE INDUSTRIES, INC.  
\* DATA TYPES \* 5300 W. 127TH STREET  
EU AT EC FW EF OT ALSIP, IL 60658  
XX XX

COMPANY# 006453 GREENWOOD CHEMICAL CO INC  
\* DATA TYPES \* 2 KLEEN WAY  
EU AT EC FW EF OT HOLBROOK, MA 02343  
XX

COMPANY# 006466 FITZPATRICK BROS INC  
\* DATA TYPES \* 625 N. SACRAMENTO BLVD  
EU AT EC FW EF OT CHICAGO, IL 60612  
XX

COMPANY# 006487 RELIANCE CHEMICAL CO.

* DATA TYPES *	5273 BROADVIEW ROAD.
EU AT EC FW EF OT	PARMA, OH 44134
XX	
COMPANY# 006658	COBITCO, INC.
* DATA TYPES *	620 SPIRIT OF ST. LOUIS BLVD
EU AT EC FW EF OT	CHESTERFIELD, MO 630051005
XX	
COMPANY# 007925	BRITE HOUSE CO
* DATA TYPES *	812 PLUMWOOD DRIVE
EU AT EC FW EF OT	SCHAUMBURG, IL 60173
XX	
COMPANY# 008000	DO-ALL CHEMICAL CORPORATION
* DATA TYPES *	630 DRIGGS AVE
EU AT EC FW EF OT	BROOKLYN, NY 11211
XX	
COMPANY# 008238	BARRIER INDUSTRIES INC
* DATA TYPES *	200 EAST MAIN ST
EU AT EC FW EF OT	PORT JERVIS, NY 12771
XX XX	
COMPANY# 008468	KOBOY AMMONIA PRODUCTS INC
* DATA TYPES *	3601 W JARVIS AVE
EU AT EC FW EF OT	SKOKIE, IL 60076
XX	
COMPANY# 008959	APPLIED BIOCHEMISTS
* DATA TYPES *	W175 N11163 STONEWOOD DRIVE
EU AT EC FW EF OT	SUITE 234
XX	GERMANTOWN, WI 53022
COMPANY# 009405	CHEMTECH DIVISION
* DATA TYPES *	AIRWICK IND INC 380 N ST
EU AT EC FW EF OT	TETERBORO, NJ 07608
XX XX	
COMPANY# 009556	ORTEX PRODUCTS INC
* DATA TYPES *	55 JACOBUS AVE.
EU AT EC FW EF OT	SO. KEARNY, NJ 07032
XX	
COMPANY# 009594	INTERCONTINENTAL CHEMICAL CORP
* DATA TYPES *	4660 SPRING GROVE AVE
EU AT EC FW EF OT	CINCINNATI, OH 45232
XX	
COMPANY# 010292	VENUS LABORATORIES, INC.
* DATA TYPES *	855 LIVELY BLVD
EU AT EC FW EF OT	WOOD DALE, IL 60191
XX XX	
COMPANY# 010495	DIRECT CHEMICAL COMPANY LTD
* DATA TYPES *	160 BROADWAY
EU AT EC FW EF OT	NEW YORK, NY 10038
XX XX	
COMPANY# 010634	ALPHA CHEMICAL SERVICES INC
* DATA TYPES *	PO BOX 431
EU AT EC FW EF OT	STOUGHTON, MA 02072
XX	
COMPANY# 010715	P & R CHEMICAL COMPANY INC
* DATA TYPES *	PO BOX 531
EU AT EC FW EF OT	METUCHEN, NJ 08840
XX	
COMPANY# 010851	DENTSPLY INTERNATIONAL INC.
* DATA TYPES *	1301 SMILE WAY
EU AT EC FW EF OT	YORK, PA 17404
XX	

COMPANY# 010882	CHEMPOWER
* DATA TYPES *	15 WING DRIVE
EU AT EC FW EF OT	CEDAR KNOLLS, NJ 07927
XX	
COMPANY# 010970	PRISON INDUSTRY AUTHORITY
* DATA TYPES *	444 N. 3RD ST. SUITE 310
EU AT EC FW EF OT	SACRAMENTO, CA 95814
XX XX	
COMPANY# 011602	MOLAR ENTERPRISES
* DATA TYPES *	1621 HENNEPIN AVE
EU AT EC FW EF OT	MINNEAPOLIS, MN 55430
XX	
COMPANY# 011613	SOUTHEASTERN SANITARY SPLY COMPANY
* DATA TYPES *	PO BOX 1541
EU AT EC FW EF OT	MONTGOMERY, AL 36102
XX	
COMPANY# 011760	EDSAN CHEMICAL COMPANY
* DATA TYPES *	438 EAST ST
EU AT EC FW EF OT	NEW HAVEN, CT 06511
XX	
COMPANY# 012010	SALEM LABORATORIES
* DATA TYPES *	8325 CHUBB RD
EU AT EC FW EF OT	NORTH VALE, MI 48167
XX	
COMPANY# 012107	FLEXO CHEMICAL CO
* DATA TYPES *	PO BOX 82
EU AT EC FW EF OT	RIVER FOREST, IL 60305
XX	
COMPANY# 012355	SOUTHWEST PIONEER CHEMICAL, INC.
* DATA TYPES *	PO BOX 787
EU AT EC FW EF OT	PONCA CITY, OK 74601
XX	
COMPANY# 013555	VALGHEM COMPANY INC
* DATA TYPES *	714720 DESMOND ST, PO BOX 338
EU AT EC FW EF OT	SAYRE, PA 18840
XX	
COMPANY# 014943	CORPORATED BRANDS SALES INC.
* DATA TYPES *	PO BOX 42653
EU AT EC FW EF OT	EVERGREEN PARK, IL 60642
XX	
COMPANY# 015010	HAMILTON SOAP & OIL PRODUCTS INC
* DATA TYPES *	51 BLEEKER ST
EU AT EC FW EF OT	PATERSON, NJ 07524
XX	
COMPANY# 018033	ORBIT CHEMICAL COMPANY INC
* DATA TYPES *	ROUTE #4, PO BOX 94
EU AT EC FW EF OT	BIRMINGHAM, AL 35210
XX	
COMPANY# 024052	CUSTOM CHEMICAL MFG COMPANY
* DATA TYPES *	PO BOX 129
EU AT EC FW EF OT	NEW BRIGHTON, PA 15066
XX	
COMPANY# 025024	WRIGHT INC. (SEE 8727)
* DATA TYPES *	PO BOX 15322
EU AT EC FW EF OT	FORT WORTH, TX 76119
XX	
COMPANY# 025581	G & G CHEMICAL CO INC
* DATA TYPES *	1333 VAN DYKE AVENUE



EU AT EC FW EF OT    SAN FRANCISCO, CA 94124  
XX

COMPANY#    027872    OHIO SOAP PRODUCTS COMPANY INC.  
\* DATA TYPES \*    3319 REGENT AVE.  
EU AT EC FW EF OT    CLEVELAND, OH 441271999  
XX

COMPANY#    029780    CENTENNIAL CHEMICALS, INC  
\* DATA TYPES \*    1094 HUFF RD NW  
EU AT EC FW EF OT    ATLANTA, GA 30318  
XX

COMPANY#    039491    NORD LABORATORIES  
\* DATA TYPES \*    845 KENNEDY STREET  
EU AT EC FW EF OT    OAKLAND, CA 94606  
XX

COMPANY#    066607    SPRAY DRIFT TASK FORCE  
\* DATA TYPES \*    1900 K STREET, NW  
EU AT EC FW EF OT    WASHINGTON, DC 20006  
XX

COMPANY#    070299    TECHNOLOGY SCIENCES GROUP INC.  
\* DATA TYPES \*    Agent for: BIOSAFE SYSTEMS LLC  
EU AT EC FW EF OT    1101 17TH ST NW, SUITE 500  
XX    WASHINGTON, DC 20036

CHEMICAL    CHEMICAL NAME  
073508    Potassium bicarbonate

COMPANY#    010772    CHURCH & DWIGHT CO INC  
\* DATA TYPES \*    469 NORTH HARRISON ST  
EU AT EC FW EF OT    PRINCETON, NJ 08543  
XX

COMPANY#    066607    SPRAY DRIFT TASK FORCE  
\* DATA TYPES \*    1900 K STREET, NW  
EU AT EC FW EF OT    WASHINGTON, DC 20006  
XX

COMPANY#    070870    H&I AGRITECH, INC  
\* DATA TYPES \*    95 BROWN ROAD, BOX 1030  
EU AT EC FW EF OT    ITHACA, NY 14850  
XX

CHEMICAL    CHEMICAL NAME  
074001    Calcium cyanide

COMPANY#    010101    SWIFT CHEM COMPANY SWIFT R & D CTR  
\* DATA TYPES \*    1919 SWIFT DR  
EU AT EC FW EF OT    OAK BROOK, IL 60521  
XX

COMPANY#    040285    DEGESCH AMERICA, INC.  
\* DATA TYPES \*    153 TRIANGLE DRIVE  
EU AT EC FW EF OT    WEYERS CAVE, VA 24486  
XX

CHEMICAL    CHEMICAL NAME  
074002    Sodium cyanide

COMPANY#    006704    USGS UPPER MIDWEST ENVIRONMENTAL SCIENCES CENTER  
\* DATA TYPES \*    Agent for: U.S. FISH AND WILDLIFE SERVICE  
EU AT EC FW EF OT    2630 FANTA REED ROAD  
XX XX XX XX XX    LA CROSSE, WI 54603

COMPANY#    066607    SPRAY DRIFT TASK FORCE  
\* DATA TYPES \*    1900 K STREET, NW  
EU AT EC FW EF OT    WASHINGTON, DC 20006  
XX

CHEMICAL    CHEMICAL NAME

**SRC**  
*Scientific & Regulatory*  
Consultants, Inc.

August 31, 2005

Tajah Blackburn, Ph. D.  
Office of Pesticide Programs, Antimicrobial Division  
USEPA Headquarters  
Ariel Rios Building -7510C  
1200 Pennsylvania Avenue, N. W  
Washington, D.C. 20460

SUBJECT: Concrobium, EPA File Symbol No. 82552-R

Dear Dr. Blackburn,

Thank you for your assistance on behalf of our client, Siamons International, Inc. ("Siamons"). Upon your request, Siamons and the testing laboratory, umedik Inc. ("umedik"), have reviewed the efficacy studies: Hard Surface Mildewstat Fungistatic Test (MRID 465589-12) and Fabric Mildewstat Fungistatic Test (MRID 465589-11). Please recall that at the time of conduct of these studies that the product use pattern was, and remains today, a non-public health use. Non-public health efficacy data is not required to be submitted (40 CFR Part 158.640 Footnote (b)(1)) to EPA. EPA Good Laboratory Practice ("GLP") (40 CFR Part 160) allows that only data that is to be submitted to EPA is required to be GLP compliant.

While the protocols for these studies stated the non-GLP status of each study due to the non-public health status of the product, umedik has stated that all aspects of GLP were in compliance during both studies with the exception of 40 CFR Part 160.35 Quality Assurance Unit (QAU). With this exception, the studies were in full compliance with EPA requirements for testing of a non-public health product. We encourage EPA to accept these studies as support for Concrobium, EPA File Symbol No. 82552-R.

We respectfully request that the Data Evaluation Report ("DER") be revised as discussed in prior correspondence to reflect the acceptance of this data, the updated labeling, removal of the notes, and removal of the requirement to add fabric claims. We greatly appreciate this revision to the DER to facilitate future interaction with other regulatory bodies. Thank you for your prompt assistance to this matter.

Sincerely,



Rhonda Jones, RM(AAM)  
President

cc: Eric Green, Siamons International, Inc.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Washington, D.C. 20460



OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES  
Antimicrobial Division

08/26/05

**SUBJECT:** PRODUCT CHEMISTRY REVIEW OF: **CONCROBIUM**

**DP Barcode:** D318256

**Reg. No. or File Symbol** 82552-R

**TGAI/Manufacturing-use Product** ☐ **OR** **End-use Product** ☒

**TO:** Adam Heyward / Lisa McKelvin  
PM Team 34

**FROM:** Juan F. Negrón, Chemist  
Product Science Branch, CT Team  
Antimicrobial Division (7510C)

**THRU:** Karen P. Hicks, CT Team Leader  
Product Science Branch  
Antimicrobial Division (7510C)

**THRU:** Michele E. Wingfield, Chief  
Product Science Branch  
Antimicrobial Division (7510C)

**APPLICANT:** Siamons International, Inc.

**Action code:** A54

**Due date:** 09/28/05

**Product Formulation**  
**Active Ingredient(s)**

Trisodium phosphate

% by wt.  
1.12

## BACKGROUND:

The registrant, Siamons International, Inc., is submitting a new registration data package for review. The non-integrated end-use product, **CONCROBIUM**, prevents mold & mildew, eliminates mold odor, and is a fungi-stat and mildew-stat.

## FINDINGS:

1. The Product Chemistry Reviewer has received the following documents:
  - Confidential Statements of Formula (CSFs), dated 05/27/05, & 08/25/05, for the basic formulation.
  - A letter, dated 05/27/05. MRID # 465589-00.
  - Labels, dated 05/26/05, & 08/26/05.
  - Trisodium phosphate justification for increased certified limits.
  - Study titled "Product Chemistry Identity and Composition." Volume 2. MRID # 465589-01.
  - Study titled "Product Chemistry Physical Properties." Volume 3. MRID # 465589-02.
  - An email, dated 08/26/05, updating the label.
2. The CSF, dated 05/27/05, for the basic formulation is obsolete.
3. The CSF, dated 08/25/05, for the basic formulation is revised.
4. The CSF and the label have the same nominal.
5. The registrant is requesting a condition of registration for the 830.1700 Preliminary Analysis. The registrant wants to do it once they start the full-scale production.
6. The registrant did not respond to the 830.6314 Oxidation/Reduction: chemical incompatibility guideline.
7. The Registrant submitted a 30 day accelerated stability study @  $50^{\circ}\text{C} \pm 2.0^{\circ}\text{C}$ .
8. See **PRODUCT CHEMISTRY (Series 830 Part A)** table below for data gap and that which requires upgraded data.

**RECOMMENDATIONS:**

1. The registrant needs to respond to the 830.6314 Oxidation/Reduction: chemical incompatibility guideline.
2. The registrant needs to perform the one-year storage stability study along with the corrosion characteristics study.

**CONCLUSION:**

The CSF, dated 08/25/05, for the basic formulation is acceptable. The CSF and the label have the same nominal. The registrant needs to submit 830.1700 Preliminary Analysis once they start the full-scale production.



## PRODUCT CHEMISTRY REVIEW

### 3. CONFIDENTIAL STATEMENT OF FORMULA

3a. Type of formulation and source registration

- Non-integrated formulation system ☒ [X]
- Are all TGAI used registered? Yes ☐ No ☐ NA ☒ [X]
- Integrated formulation system ☐ []
- if "ME-TOO", specify EPA Reg. # of existing product:

3b. Clearance of inerts for non-food or food use:

Cleared for food use under 40 CFR §180.1001: Yes ☒ [X] No ☐ NA ☐ []

3c. Physical state of the product: Liquid.

3d. The chemical IDs and analytical information (including that for the TGAI), density, pH, and flammability are consistent with that given in 830.1000, Series A and 830.7300, .7000 and .6315 respectively: Yes ☒ [x] No ☐ []

3h. NCs and CLs are: acceptable ☒ [x] Not acceptable ☐ []

3i. Active ingredient (s)	NC	UCL	LCL
A. Trisodium phosphate	1.12	1.23	1.00

3j. For products produced by an integrated formulation system:

- All impurities of toxicological significance have a UCL?  
Yes ☐ No ☐ Not applicable ☒ [X]
- All impurities of  $\geq 0.1\%$  in the product have been identified?  
Yes ☐ No ☐ Not applicable ☒ [X]

4. PRODUCT LABEL

4a. The active ingredients statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA? Yes [x] No []

4b. The formulation contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- Sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

4c. If Yes to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [] No [] Not applicable [X]

4d. The appropriate warning statement regarding flammability or explosive characteristics of the product are listed on the label?  
Yes [ ] No [ ] Not applicable [X]

4e. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses? PR Notice 84-1 Yes [] No [] Not applicable [x]  
PR Notice 83-3 Yes [x] No [] Not applicable []

4f. Does the product require an expiration date at which time the NC falls below the LCL (based on the one year storage stability data or other information)?  
Yes [] No [] Pending [X]

5a

**PRODUCT CHEMISTRY (Series 830 Part A)**

Group A	Acceptance of Information	MRID No.
830.1550 Chemical ID	A	465589-01
830.1600 Description of Materials	A	465589-01
830.1620 Description of Production Process <sup>2</sup>	A	465589-01
830.1650 Description of Formulation Process	A	465589-01
830.1670 Discussion of Impurities	A	465589-01
830.1700 Analysis <sup>5</sup>	G <sup>5</sup>	465589-01
830.1750 Certified Limits	A	465589-01
830.1800 Analytical Method for AIs	A	465589-01

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; NR= not required,

G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

<sup>1</sup>See Confidential Appendix A for additional information

<sup>2</sup>For MP/EP products produced by an integrated formulation system.

<sup>3</sup>For products from a TGAI or MP.

<sup>4</sup>May be waived unless actual/possible impurities are of toxicological concern.

<sup>5</sup>**Five batch analysis required for products produced by an integrated formulation system. The registrant is requesting a condition of registration. The registrant wants to do it once they start the full-scale production.**

<sup>6</sup>If different from standard CLS recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

<sup>7</sup>Abbreviate method used as follows: gas chromatography (GC), infrared (IR),

Group B	Acceptance of data	Value or qualitative description	MRID No.
830.6302 Color	A	Colorless	465589-02
830.6303 Physical State	A	Clear liquid	465589-02
830.6304 Odor	A	Odorless	465589-02
830.6313 Stability to normal & elevated temp., metals, & metal ions	NA		
830.6314 Oxidation/Reduction: chemical incompatibility.	G		
830.6315 Flammability/Flash Pt	A	Non-flammable	465589-02
830.6316 Explodability	A	Potentially not explosive.	465589-02
830.6317 Storage stability <sup>1</sup>	U <sup>1</sup>	Stable after 1 month @ 50 °C ± 2.0 °C	465589-02
830.6319 Miscibility	A	Not to be used in petroleum solvents.	465589-02
830.6320 Corrosion characteristics <sup>1</sup>	U <sup>1</sup>	No reaction during 1 month.	465589-02
830.6321 Dielectric breakdown voltage	A	Not to be used around electrical equipment.	465589-02
830.7000 pH	A	11.1 @ 25 °C	465589-02
830.7050 UV/Visible absorption	NA		
830.7100 Viscosity	A	0.00485 Cst @ 20 °C	465589-02
830.7200 Melting point/melting range	NA		
830.7220 Boiling point/ boiling range	NA		
830.7300 Density/sp. gravity	A	1.022 g/ml @ 20 °C	465589-02
830.7370 Dissociation constants in water	NA		
830.7520 Particle size, fiber length, & diameter distribution	NA		
830.7550 Partition coefficient(n-octanol/water), shake flask method	NA		
830.7560 Partition coefficient(n-octanol/water), generator column method	NA		
830.7570 Partition coefficient(n-octanol/water),	NA		
830.7840 Water solubility: Column elution method; shake flask method	NA		
830.7860 Water solubility, generator column method	NA		
830.7950 Vapor pressure	NA		

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; NR= Not required  
 G=data gap; U=requires upgrading; W=waived; E=EPA estimate. <sup>1</sup>= Registrant must perform one year study.  
 redox = Oxidizing / Reduction; Unless otherwise indicated, the property should be at 25°C.

**Synonym Information For Ingredient**  
**081405 / 87-90-1 / Trichloro-s-triazinetriene**

Name	Type
1,3,5-Triazine-2,4,6(1H,3H,5H)-trione, 1,3,5-trichloro-	Other Systematic
1,3,5-Trichloro-s-triazinetriene	Other Systematic
ACL 85	Trade
N,N',N''-Trichloroisocyanuric acid	Other Systematic
Trichloro-s-triazinetriene	Other Common
Trichloroisocyanuric acid	Other Systematic
Total Rows: 6	





SHayes  
<SHayes@srcconsultants.com>

08/26/2005 09:04 AM

Please respond to  
SHayes@srcconsultants.com

To Adam Heyward/DC/USEPA/US@EPA

cc Juan Negron/DC/USEPA/US@EPA, Ann Cozad  
<acozaad@srcconsultants.com>

bcc

Subject EPA Reg. No. 82552-R

Adam,

During the chemistry review a discrepancy was noted between the CSF and the label claim. Attached is a label that reflects the active ingredient level of 1.12% TSP. This label also has the reapplication period requested by efficacy.

Please update your files to reflect this as the most current label.

Sally Hayes  
Scientific & Regulatory Consultants, Inc.  
260-244-6270  
www.srcconsultants.com



Concrobium Label 082405.doc

**Pending and Active Registrations For**  
**Ingredient**  
**073506 / 497-19-8 / Sodium carbonate**

Registration #	Registration Name	Company #	Company Name	Current Status	% Ac Ingr
11715-34	MAGIC GUARD CLEANER/DISINFECTANT	11715	SPEER PRODUCTS INC	<u>Active - Registered (10-Mar- 1975)</u>	3
15136-10	MED-CHEM GERMICIDAL SOLUTION	15136	MEDICAL CHEMICAL CORP.	<u>Active - Registered (20-Dec- 1967)</u>	.416
56938-3	FRESH & CLEAN	56938	ABC CORPORATION	<u>Active - Conditionally Registered (04-Dec- 1986)</u>	1
02DA07		800056	USDA	<u>Active - Issued (09- Apr-2002)</u>	
05DA03				<u>Pending - Under Review (13- May-2005)</u>	
99DA05		800056	USDA	<u>Active - Issued (15- Apr-1999)</u>	
Total Rows: 6					

**Unique Approved Site Information For**  
**Ingredient**  
**073506 / 497-19-8 / Sodium carbonate**

Site Code	Site Name	Status
710005102	FOOD PROCESSING EQUIPMENT	Approved
710005202	FOOD PROCESS PLANT PREMISES	Approved
720005201	EATING EST PREMISES	Approved
720065103	EATING EST EQUIPMENT	Approved
720065108	EATING EST UTENSILS	Approved
720065111	EATING EST FOOD CONTACT SURFACES	Approved
740006601	HOSPITAL PREMISES	Approved
740086602	HOSPITAL CRITICAL PREMISES	Approved
740110001	SURGICAL INSTRUMENTS	Approved
740110002	HYPODERMIC NEEDLES/SYRINGES	Approved
740116601	DENTAL INSTRUMENTS	Approved
740116602	HOSPITAL INSTRUMENTS	Approved
740116801	LABORATORY INSTRUMENTS	Approved
740120009	HOSPITAL CRITICAL RUBBER/PLASTIC ITEMS	Approved
740136605	HOSPITAL MATERIALS	Approved
770000026	INDUSTRIAL PREMISES	Approved
770000028	INSTITUTIONAL PREMISES	Approved
770020030	INDUSTRIAL EQUIPMENT	Approved
770020033	INSTITUTIONAL EQUIPMENT	Approved
880030002	BATHROOM PREMISES	Approved
890000005	GARBAGE STORAGE PREMISES	Approved
890010001	GARBAGE CANS	Approved
900180005	ENVIRONMENTAL INANIMATE HARD SURFACES	Approved
Total Rows: 23		

**Site/Pest Information For  
Product Registration - Section 3  
10118-1**

**Site Information**

Site Code	Site Name	Status	Status Reason	Status Date	Major Use?	Arid Restricted Entry Interval?
650306201	WHIRLPOOL BATH SURFACES	Approved		30-Jul-1968	N	N
770000028	INSTITUTIONAL PREMISES	Approved		30-Jul-1968	N	N
770000035	LOCKER ROOM PREMISES	Approved		30-Jul-1968	N	N
770020001	ATHLETIC EQUIPMENT	Approved		30-Jul-1968	N	N
770020013	GYMNASIUM MATS	Approved		30-Jul-1968	N	N
770020033	INSTITUTIONAL EQUIPMENT	Approved		30-Jul-1968	N	N
Total Rows: 6						

**Pest Information**

Pest Name	Status	Status Reason	Status Date
ANIMAL PATHOGENIC BACTERIA (G- AND G+ VEGETATIVE)	Approved		30-Jul-1968
ANIMAL PATHOGENIC FUNGI	Approved		30-Jul-1968
PSEUDOMONAS SPP.	Approved		30-Jul-1968
Total Rows: 3			

Reg # 10118-1

PM 31

17-2

**Mueller**

# **WHIZZER<sup>®</sup>**

## **Mat Cleaner & Disinfectant**

**A potent multipurpose germicide and concentrated cleaner for wrestling mats and other athletic equipment.**

**DIRECTIONS:** Use one (1) pint of this concentrate and dilute with water to make one (1) gallon of ready to use Whizzer Mat Cleaner and Disinfectant<sup>™</sup>. Before using this product remove heavy soil deposits or gross filth from surfaces to be cleaned with broom or other suitable device. Use sponge or towel and apply the newly mixed Whizzer Mat Cleaner and Disinfectant<sup>™</sup> freely over mat. Wipe dry with clean dry towel. This product when used in the above described method can be used on floors, training room whirlpools, taping benches, locker room area walls and athletic training room furniture.

Active	ACTIVE INGREDIENTS	
	METHYLODECYLBENZYL TRIMETHYL AMMONIUM CHLORIDE	0 3764%
	METHYLODECYLXYLENE BIS (TRIMETHYL AMMONIUM CHLORIDE	0 0940%
	INERT INGREDIENTS	99 5296%
Inert	EPA REG. NO. 10118-1	TOTAL 100 0000%

**CAUTION — KEEP OUT OF REACH OF CHILDREN, HARMFUL IF SWALLOWED — SEE BACK PANEL FOR ADDITIONAL CAUTIONS**

**RINSE EMPTY CONTAINER AND DISCARD IT**

**NET CONTENTS 1 GALLON** **EPA EST. no. 10118-WI-1**



# WHIZZER<sup>®</sup>

## Mat Cleaner & Disinfectant

Caution — Keep out of reach of children. Whizzer Mat Cleaner and Disinfectant™ may cause skin and eye irritation. Harmful if swallowed. Avoid contact with the skin or eyes. Do not take internally. In case of contact flush immediately with plenty of water and get immediate medical attention. Avoid contamination of food. Internal antidote — If swallowed, do not induce vomiting, drink large quantities of fluid and call a physician immediately.

When properly used as per direction on front panel, Whizzer Mat Cleaner and Disinfectant™ destroys the following organisms on inanimate surfaces...

### Organism Bacteria

Salmonella typhosa

Staphylococcus aureus

Pseudomonas aeruginosa

### Fungi

Trichophyton mentagrophytes

(Interdigitale)

Manufactured by

 **Mueller Sports Medicine, Inc.**  
Prairie du Sac, WI 53578 U.S.A.

77



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

FAX TRANSMITTAL

DATE: AUGUST 11, 2005

TO: Sally Hayes  
Scientific & Regulatory Consultants, Inc.

260/244-6270  
260/244-6273 fax

FROM: Adam Heyward

703/308-6422  
703/308-8481 fax

SUBJECT: 82552-R (CONCROBIUM)

COMMENTS

See attached copy of EPA/AD Efficacy review for the above proposed product. Data is not acceptable.  
Note the PRIA due date for the above product is September 28, 2005. Please call me to discuss.

A handwritten signature in cursive script, reading "Adam Heyward", is written over a horizontal line.

Adam Heyward  
Product Manager 34  
Regulatory Management Branch II  
Antimicrobials Division (7510C)  
Email: [heyward.adam@epa.gov](mailto:heyward.adam@epa.gov)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Original date: July 5, 2005  
Revised date: September 8, 2005

**MEMORANDUM**

**Subject:** Efficacy Review for EPA Reg. No. 82552-R, Concrobium  
DP Barcode: 318258

**From:** Tajah L. Blackburn, Ph.D., Microbiologist  
Efficacy Evaluation Team  
Product Science Branch  
Antimicrobials Division (7510C)

*[Signature]* 9/8/05

**Thru:** Nancy Whyte, Acting Team Leader *NW 9/8/05*  
Efficacy Evaluation Team  
Product Science Branch  
Antimicrobials Division (7510C)

**To:** Adam Heyward PM 34/ Lisa McKelvin  
Regulatory Management Branch II  
Antimicrobials Division (7510C)

**Applicant:** Siamons International, Inc.  
Toronto, ON M9W 1A4

**Formulation from Label**

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Trisodium Phosphate.....	1.19%
<u>Other Ingredient(s)</u> .....	<u>98.81%</u>
Total	100.00%

## I BACKGROUND

The product, Concrobium (EPA Reg. No. 82552-R), is a new product. The applicant requested to register the product as a fungistat designed to prevent and inhibit growth of mold, fungus and mildew on floors, walls, and other hard nonporous interior building surfaces, until the cause of such growth is identified. Per the proposed label, "this product should be used in those cases where **visible microbial growth** has been detected (or conditions are likely to immediately result in such growth) as part of a program that removes that growth and identifies and corrects the conditions that led to that growth. "As current guidance directs, claims of this nature are considered non-public health. Therefore, efficacy data is reviewed and maintained on file; however performance standards are silent governing acceptance or rejection of efficacy data. Studies were conducted at umedik, Inc., located at 36 Meteor Drive, Toronto, Ontario, Canada, M9W 1A4.

This data package contained a letter from the applicant to EPA (dated May 27, 2005), two efficacy (MRID No. 465589-11 and -12), an Efficacy Discussion (MRID No. 465589-10), and the proposed label. A revised proposed label was submitted to replace previous label submission.

Note— Efficacy testing was not conducted under the framework of 40 CFR 160. An explanation was provided from the registrants detailing study/guideline deviations. According to the document, "...all aspects of GLP were in compliance during both studies [MRID No. 465589-11 and 465589-12] with the exception of 40 CFR Part 160.35 Quality Assurance Unit (QAU)."

## II USE DIRECTIONS

This product is designed for use on floors, walls, and other **hard, nonporous** interior surfaces in basements, bathrooms, vacation homes, boat interiors, and areas under construction. Directions on the proposed label provided the following information regarding the use of the product:

Concrobium can be applied by hand-spray, paintbrush, roller, immersion, airless sprayer or pressure fogger (approximately 400 square feet per gallon). To maintain protection against regrowth, do not rinse or wash surfaces after treatment. Re-application of Concrobium may be required if surfaces are washed or painted or are otherwise directly exposed to water.

Preventive Treatment— To inhibit the growth of mold and mildew on surfaces: (1) Apply Concrobium on area until evenly wet; (2) To promote drying and to avoid residue marks, use a clean cloth or paper towel to wipe off excess wetness; (3) Allow treated surfaces to dry completely.

### III AGENCY STANDARDS FOR PROPOSED CLAIMS

Algaecides, slimicides, preservatives, deodorizers, and other products expressly claiming control of microorganisms of economic or aesthetic significance not directly related to human health do not require efficacy data. However, adequate dosage recommendations and complete directions for use must be provided on product label. These Agency standards are presented in DIS/TSS-16.

### IV COMMENTS ON SUBMITTED EFFICACY STUDIES

**1. MRID No. 465589-11, "Fabric Mildew Fungistatic Test" for Siamons Mold Control, by Peter Lea, PhD. Study conducted at umedik, Inc. Study completion date— not disclosed. Experimental End Date— August 9, 2004.**

This study was conducted against *Aspergillus niger* (ATCC 6275) and *Penicillium variable* (ATCC 32333). Three lots were (Lot Nos. JJ040113-01/01/01, JJ040210-01/01/01, and JJ040628-01/01/02) of the product Siamons Mold Control were tested according to the test method as published in EPA's Pesticide Assessment Guidelines, Subdivision G: Product Performance, Section 93-15 (a) and 93-30 (I) (Item 1: Fabric Mildew Fungistatic Test Method, November 1982). Two lots (JJ040113-01/01/01 and JJ040210-01/01/01) were designated as the aged products (i.e.,  $\geq 60$  days old). The product was received ready-to-use. The fungi were inoculated from stock cultures onto neopeptone agar plates and incubated at 25°C for eight days. Upon maturity, the spores were removed, and the suspensions were filtered through sterile cotton to remove the hyphae and hyphal fragments. Strips measuring 25 x 75 mm each were cut from unbleached cotton fabric. Each strip weighed ~ 0.27 grams (143.99 g/m<sup>2</sup>) to conform to the EPA guidelines. All strips were autoclaved, with a subsequent soak in glycerol nutrient solution for 3 minutes. Each fabric strip was dried under sterile conditions before use. Ten dried, nutrient saturated fabric strips per lot were evaluated. Using a spray bottle, each lot of Siamons Mold Control was sprayed 4 to 5 times on both sides, from a distance of 6-8 inches, onto the fabric strips. The strips were hung in the sterile laminar air flow hood. Ten untreated fabric strips were sprayed with saline solution in place of the test agent for the untreated control. All samples were allowed to dry before inoculation. Equal volumes of  $5 \times 10^6$  conidia/ml suspension of *A. niger* and *P. variable* were mixed together and agitated. Each side of each fabric strips was lightly sprayed to inoculate the mixed conidial suspension using a DeVilbiss atomizer. The fabric samples were suspended in individual 500 ml jars containing approximately 90 ml sterile water, and incubated at 28±2°C. Observations were made and recorded weekly for 4 weeks (minimally 7, 14, 21 and 28 days). The presence or absence of observable mold on the fabric strips was the criterion for determining the efficacy of the test agent. When no visible growth was evident at the end of the test period, the fabric strips were examined microscopically. Controls included those for purity and sterility.

Note— According to MRID No. 465589-10, Siamons Mold Control is identical to Concrobium, the subject of the current efficacy review.

**2. MRID No. 465589-12, "Hard Surface Mildew Fungistatic Test" for Siamons Mold Control, by Peter Lea, PhD. Study conducted at umedik, Inc. Study completion date— not disclosed. Experimental end date— July 16, 2004.**

The study was conducted against *Aspergillus niger* (ATCC 6275). Three lots (Lot Nos. JJ040113-01/01/01, JJ040210-01/01/01, and JJ0404628-01/01/02) of the product, Siamons Mold Control, were tested using the were tested according to the method published in Pesticide Assessment Guidelines, Subdivision G: Product Performance, Section 93-15 (a) and 93-30 (I) (Item 2: Hard Surface Mildew Fungistatic Test Method, November 1982). Two lots (JJ040113-01/01/01 and JJ040210-01/01/01) were designated as the aged products (i.e.,  $\geq 60$  days old). The product was received ready-to-use. *A. niger* was inoculated from stock cultures onto neopeptone agar plates and incubated at  $25 \pm 2^\circ\text{C}$  for eight days. Upon maturity, the spores were removed and the suspensions were filtered through sterile cotton to remove hyphae and hyphal fragments. Ten carriers (glazed ceramic tiles) per lot were sprayed with the test substance using a spray bottle. Each tile was sprayed 4 to 5 times to ensure complete wetting. The distance from the nozzle of the spray bottle to a tile was 10 centimeters. Post spraying, the carriers were placed in a vertical or near vertical position in a separate Petri dish to permit excess liquid to drain. Five tiles were placed in each of two sterile Petri dishes with lids ajar and allowed to dry for 30 minutes at  $37^\circ\text{C}$ . Ten untreated tiles were placed in Petri dishes with lids ajar and allowed to dry at  $37^\circ\text{C}$ . Glazed ceramic carriers were inoculated with a  $5.0 \times 10^6$  conidia/ml, utilizing a #152 DeVilbiss atomizer while maintaining agitation. The tiles, located in Petri dishes, were returned to  $37^\circ\text{C}$  incubator and dried for 30 minutes until visibly dry. Carriers were subsequently placed in individual Petri dish containing harden sterile water agar for 7 days at  $25 \pm 2^\circ\text{C}$  with 95% humidity. Post incubation, the plates were observed for the presence or absence of macroscopic fungal growth. If no visible growth was evident at the end of the test period, the carrier was examined microscopically. Control included those for purity and sterility.

Note— According to MRID No. 465589-10, Siamons Mold Control is identical to Concrobium, the subject of this current efficacy review.



## V RESULTS

Siamons Mold Control, Lot No. JJ040113-01/01/01 (>60 days old)

MRID Number	Organisms	Carrier Number	Test Results – Visual/Microscopic Growth/Carrier				Control Inoculum  (conidia/ml)
			Days				
			7	14	21	28	
465589-11	<i>A. niger</i>	1-10	0%	0%	0%	0%	5.0 x 10 <sup>6</sup>
	<i>P. variable</i>						5.1 x 10 <sup>6</sup>

Note– Untreated control 100% visual growth on carrier.

Saimons Mold Control, Lot JJ040210-01/01/01 (60 days old)

Common Mold Control, Lot 65516215 3/15/07 (60 days old)							
MRID Number	Organisms	Carrier Number	Test Results – Visual/Microscopic Growth/Carrier				Control Inoculum  (conidia/ml)
			Days				
			7	14	21	28	
465589-11	<i>A. niger</i>	1-10	0%	0%	0%	0%	5.0 x 10 <sup>6</sup>
	<i>P. variable</i>						5.1 x 10 <sup>6</sup>

Note– Untreated control 100% visual growth on carrier.

Siamons Mold Control, Lot JJ040628-01/01/02

Diamond Media Control, Lot: 666-16626 3/16/1992							
MRID Number	Organisms	Carrier Number	Test Results – Visual/Microscopic Growth/Carrier				Control Inoculum  (conidia/ml)
			Days				
			7	14	21	28	
465589-11	<i>A. niger</i>	1-10	0%	0%	0%	0%	$5.0 \times 10^6$
	<i>P. variable</i>						$5.1 \times 10^6$

Note– Untreated control 100% visual growth on carrier.

MRID Number	Organism	Carrier Number	Test Results – Visual/Microscopic Growth/Carrier				Control Inoculum (conidia/ml)
			7 Days Exposure				
			JJ040112-01/01/01	JJ040210-01/01/01	JJ040628-01/01/02	Control	
465589-12	<i>A. niger</i>	1-10	0%	0%	0%	100%	5.0 x 10 <sup>6</sup>

## VI CONCLUSIONS

1. The submitted efficacy data (MRID 465589-11) **support** the use of the product, Siamons Mold Control (ready-to-use), as a fungistat/mildewstat against *Aspergillus niger* and *Penicillium variable* on surfaces composed of fabric in the absence of a soil load for a period of extended wetness. The study was not conducted according to GLP guidelines/recommendations (40 CFR 160), however the study deviation, in this case, was not significant.
2. The submitted efficacy data (MRID 465589-12) **support** the use of the product, Siamons Mold Control (ready-to-use), as a fungistat/mildewstat against *Aspergillus niger* on hard, non-porous surfaces in the absence of soil for a period of extended wetness. The study was not conducted according to GLP guidelines/recommendations (40 CFR 160), however the study deviation, in this case, was not significant.

## VII LABEL COMMENTS/RECOMMENDATIONS

1. The proposed label claims are acceptable regarding the use of, Concrobium, as an effective fungistat/mildewstat on hard, non-porous surfaces in the absence of soil when applied for a period of "extended wetness". Re-application directions, as requested, were included on the revised label.
2. On the revised proposed label (under Reapplication section) determine whether "re-application" or "reapplication" will be used, for consistency.

\*\*\*\*\*  
\*\*\* TX REPORT \*\*\*  
\*\*\*\*\*

TRANSMISSION OK

TX/RX NO 0840  
CONNECTION TEL 912602446273  
SUBADDRESS  
CONNECTION ID  
ST. TIME 08/26 12:38  
USAGE T 02'33  
PGS. 9  
RESULT OK



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WASHINGTON, D.C. 20460

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PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

## FAX TRANSMITTAL

**DATE:** August 26, 2005

**TO:** Sally Hayes  
Agent for Siamons International, Inc.  
**TELEPHONE #** (260) 244-6270  
**FAX #** (260) 244-6273

**Product Name:** CONCROBIUM  
EPA File Symbol No. 82552-R

**FROM:** ADAM HEYWARD  
**TELEPHONE #:** (703) 308-6422  
**FAX #:** (703) 308-6466

**General comments:**

Attached is a copy of the acute tox review dated August 23, 2005 for CONCROBIUM. The acute tox profile is acceptable. We are currently working on your revised product chemistry information/labeling. I will talk with Dr. Blackburn on Monday 8/29 concerning the efficacy review.

  
Adam Heyward



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**FAX TRANSMITTAL**

**DATE:** August 26, 2005

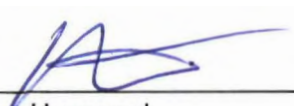
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Adam Heyward  
Product Manager 34  
Regulatory Management Branch II  
Antimicrobials Division  
email: heyward.adam@epa.gov



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

August 23, 2005

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 82552-R  
DP Barcode: D318257  
Case No:

To: Adam Heyward PM 34 / Lisa McKelvin, Team Reviewer  
Regulatory Management Branch  
Antimicrobials Division (7510C)

From: Robert A. Turpin, Jr., Scientist *R.T.*  
Chemistry/Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510C)

*[Handwritten signature]*  
*8/23/05*

Michele E. Wingfield, Chief  
Product Science Branch  
Antimicrobials Division (7510C)

Applicant: Siamons International, Inc.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Trisodium phosphate .....	1.19
<u>Other Ingredient(s):</u> .....	<u>98.81</u>
Total:	100%

BACKGROUND: The applicant has submitted an application for registration of its product, Concrobium. In support of the application, the applicant has submitted test reports responding to the requirements of OPPTS Test Guidelines for acute toxicity studies, 870.1100, -1200, -1300, -2400, -2500, and -2600.

RECOMMENDATIONS (PSB findings):

The acute toxicity profile for Reg. No. 82552-R is currently:

acute oral toxicity	IV	Acceptable
acute dermal toxicity	IV	Acceptable
acute inhalation toxicity	IV	Acceptable
primary eye irritation	IV	Acceptable
primary skin irritation	IV	Acceptable
dermal sensitization	Non-sensitizer	Acceptable

LABELING:

Date: August 23, 2005

ID #: 82552-R

Signal Word: [Not required]

First Aid Statement: [Not required]



# DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§ 81-1, 870.1100)

**Product Manager:** Adam Heyward  
**MRID No.:** 465589-04

**Reviewer:** Robert Turpin  
**Study Completion Date:** 11/17/04  
**Report No.:** 8489-04

**Testing Laboratory :** Stillmeadow, Inc.  
**Authors :** Janice O. Kuhn

**Quality Assurance (40 CFR §160.12):** Statement provided.

**Test Material:** Simons Mold Control

**Species:** Rat  
**Age:** Young adults  
**Weight:** 177-181 g  
**Source:** Texas Animal Specialties

## Conclusion:

1. **LD<sub>50</sub> (mg/kg):**                      **Males = NA**  
   **Females = >5,000**  
   **Combined = NA**  
2. **The estimated LD<sub>50</sub> is >5,000 mg/kg**  
3. **Tox. Category: IV**                      **Classification: Acceptable**

**Procedure (Deviations from §81-1):** None stated.

## Results:

Dosage (mg/kg)	(Number Deaths/Number Tested)		
	Males	Females	Combined
5,000	NA	0/3	0/3

**Observations:** Each of the animals gained weight. No signs of toxic effect were noted.

**Gross Necropsy:** No gross abnormalities were noted.



## DATA REVIEW FOR ACUTE INHALATION TOXICITY (§81-3, 870.1300)

**Product Manager:** Adam Heyward

**MRID No.:** 465589-06

**Reviewer:** Robert Turpin

**Study Completion Date:** 12/21/04

**Report No.:** 8491-04

**Testing Laboratory:** Stillmeadow, Inc.

**Author:** Lori Carter

**Quality Assurance (40 CFR §160.12):** Statement provided.

**Test Material:** Siamons Mold Control

**Concentration:** 2.28 mg/L

**Species:** Rat

**Weight:** Males: 262-317 g; Females 195-210 g

**Age:** ~ 8 weeks

**Source:** Texas Animal Specialties

### Summary:

1. **LC<sub>50</sub> (mg/L):** Males = > 2.28

Females = >2.28

Combined = >2.28

2. **The estimated LC<sub>50</sub> is** >2.28 mg/L

3. **MMAD:** 2.9 µm

4. **Tox. Category:** IV

**Classification:** Acceptable

**Procedure (Deviation From §81-3):** None stated.

### Results:

#### Reported Mortality

Exposure Concentration	(NUMBER DEATHS/NUMBER TESTED)		
	Males	Females	Combined
2.28 mg/L	0/5	0/5	0/10

Chamber Atmosphere			
Dose Level	MMAD	GSD	particles <
2.28 mg/L	2.9 µm	3.8 µm	16
	µm	µm	

Chamber Environment	
Chamber Volume	500 L
Airflow	195 Lpm
Temperature	65 ° F
Relative Humidity	67%

**Clinical Observations:** Male and female animals exhibited piloerection and decreased activity through day one after which showed no signs of abnormalities through end of test and observation period.

**Gross Necropsy Findings:** No abnormalities observed.

# DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

**Product Manager:** Adam Heyward

**Reviewer:** Robert Turpin

**MRID No.:** 465589-07

**Study Completion Date:** 11/17/04

**Report No.:** 8492-04

**Testing Laboratory:** Stillmeadow, Inc.

**Author(s):** Janice O. Kuhn

**Quality Assurance (40 CFR §160.12):** Statement provided.

**Test Material:** Siamons Mold Control

**Dosage:** 0.1 ml

**Species:** Rabbit

**Sex:** 2 males, 1 female

**Weight:** Males: 2.300-2.650 kg; Female: 2.400 kg

**Age:** ~ 12 weeks

**Source:** Nicols Rabbitry Inc.

## Summary:

1. **Toxicity Category:** IV
2. **Classification:** Acceptable

**Procedure (Deviations From §81-4):** None noted.

## Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Corneal Opacity	0/3	0/3	0/3	0/3	---	---	---	---
Iritis	0/3	0/3	0/3	0/3	---	---	---	---
Conjunctivae								
Redness	0/3	0/3	0/3	0/3	---	---	---	---
Chemosis	0/3	0/3	0/3	0/3	---	---	---	---
Discharge	0/3	0/3	0/3	0/3	---	---	---	---

--- = no observations at this point

**DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)**

**Product Manager:** Adam Heyward  
**MRID No.:** 465589-08

**Reviewer:** Robert Turpin  
**Study Completion Date:** 11/1/04  
**Report No.:** 8493-04

**Testing Laboratory:** Stillmeadow, Inc.  
**Author:** Janice O. Kuhn

**Quality Assurance (40 CFR §160.12):** Statement provided.

**Test Material:** Siamons Mold Control  
**Dosage:** 0.5 ml

**Species:** Rabbit

**Age:** ~ 13 weeks

**Sex:** 1 male; 2 females

**Weight:** Male: 2.150 kg; Female: 2.100-2.200 kg

**Source:** Nicols Rabbitry Inc.

**Summary:**

1. **Toxicity Category:** IV
2. **Classification:** Acceptable

**Procedure (Deviations From §81-5):** None noted.

**Results:** There were no signs of irritation. The primary Irritation Index score was 0.

**Special Comments:** None.



## **DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6, 870.2600)**

**Product Manager:** Adam Heyward

**MRID No.:** 465589-09

**Reviewer:** Robert Turpin

**Study Completion Date:** 12/1/04

**Report No.:** 8494-04

**Testing Laboratory:** Stillmeadow, Inc.

**Author:** Janice O. Kuhn

**Quality Assurance (40 CFR §160.12):** Statement provided.

**Test Material:** Siamons Mold Control

**Positive Control Material:** alpha-hexylcinnamaldehyde:olive oil

**Species:** Mouse

**Weight:** 20.5-28.5 g

**Age:** ~ 10 weeks

**Source:** Harlan Sprague-Dawley

**Method:** Local Lymph Node Assay

### **Summary:**

- 1. This Product is not a dermal sensitizer.**
- 2. Classification:** Acceptable

**Procedure (Deviation From §81-6):** None noted.

**Procedure:** Five female mice were selected for each of three test Groups. On days 1, 2, and 3 the animals in each of the groups received a 25 µl dose of an appropriate dilution (25% or 50%) of the test substance, or the undiluted test substance, to the dorsum of both ears. Control animals were treated in the same way with the vehicle, only. Following a 2 day rest period the test and control animals were injected in the tail with 250 µl of 0.01 M phosphate-buffered saline containing 20 µCi of [methyl, 1<sup>1</sup>, 2<sup>1-3</sup>H] Thymidine. Five hours after the injection, the animals were sacrificed, the draining auricular lymph nodes were excised and pairs from each animal were processed.

**Results:** The product produced a stimulation index of <3 in all groups of test animals, and is not considered a sensitizer.

## ACUTE TOX ONE-LINER

1. PC CODE: 076406
2. CURRENT DATE: 8/23/05
3. TEST MATERIAL: Trisodium phosphate (Concrobium)

Study/Species/Lab/ Study#/Date	MRID No.	Results	Tox. Cat.	Core Grade
acute oral toxicity /Rat/ Stillmeadow/ 8489-04/ 11-17- 04	465589-04	LD <sub>50</sub> (mg/kg) = >5,000	IV	A
acute dermal toxicity /Rabbit/ Stillmeadow/ 8490-04/ 11-18- 04	465589-05	LD <sub>50</sub> (mg/kg) = >5050	IV	A
acute inhalation toxicity / Rat/ Stillmeadow/ 8491-04/ 12-21- 04	465589-06	LC <sub>50</sub> (mg/L) = 2.28	IV	A
primary eye irritation /Rabbit/ Stillmeadow/ 8492-04/ 11-17- 04	465589-07	Not an irritant	IV	A
primary skin irritation / Rabbit/ Stillmeadow/ 8493-04/ 11-1-04	465589-08	Not an irritant	IV	A
dermal sensitization / Mouse/ Stillmeadow/ 8494-04	465589-09	Non-sensitizer	---	A

A = Acceptable  
 U = Unacceptable  
 S = Supplementary  
 V = self-Validated



SHayes  
<SHayes@srcconsultants.com>

08/24/2005 02:08 PM

Please respond to  
SHayes@srcconsultants.com

To Adam Heyward/DC/USEPA/US@EPA

Tajah Blackburn/DC/USEPA/US@EPA, Rhonda Jones

cc <rjones@srcconsultants.com>, Eric Green

<egreen@siamons.com>

bcc

Subject Concrobium, EPA File Symbol 82552-R

Adam,

Thank you for providing the efficacy DER for Concrobium, EPA File Symbol 82552-R. Rhonda Jones and Taja Blackburn have discussed the comments. We have provided Taja with a GLP advisory that indicates that non-public health data does not have to be conducted under GLPS. She is going to discuss this with her management and will let us know the outcome of that decision.

If there is agreement that the studies did not have to be conducted under GLPs, we requested that the DER be rewritten to correctly reflect this. We like to provide EPA DERs with California and foreign agencies so it is important that all information is correctly reflected. Rhonda also discussed the rationale behind why the fabric surfaces were not included on the labeling, and requested that Label Comments #2 on Page 6 be deleted from the DER.

Finally, to address the labeling comment about re-treatment we have added a re-application section to the label. Attached is a copy of the revised label.

Have the chemistry and acute toxicology reviews been completed? Have any other issues been raised that we can address now?

I look forward to your response.

Sally Hayes  
Scientific & Regulatory Consultants, Inc.  
260-244-6270  
www.srcconsultants.com



Concrobium Label 082405.doc

## CONCROBIUM

*{Front panel; marketing claims may be used on any panel}*

- Prevents mold and mildew
- Eliminates mold odor
- Contains no ammonia, bleach, alcohol or acid
- Will not damage most surfaces
- Fungistat and Mildewstat

### ACTIVE INGREDIENT

Trisodium Phosphate .....1.19%

OTHER INGREDIENTS.....98.81%

TOTAL 100.00%

Keep Out of Reach of Children

Net Contents 25.4 oz./800 mL  
1 Gallon/3.8 L

EPA Reg. No. XXXXX-XXX  
EPA Est. No. XXX-CN-01

Directions for Use must be read completely prior to using this product.

Siamons International Inc.  
Toronto, ON M9W 1A4

*{Optional marketing claims, may be used on any panel}*

- CONCROBIUM's patented technology encapsulates mold and fungal spores with a microscopic coating that inhibits its growth. Treated surfaces retain a protective barrier that will prevent the growth of mold and mildew.
- For use on most indoor surfaces.
- Helps prevent mold growth in places vulnerable to mold, including:
  - Basements
  - Bathrooms
  - Vacation homes
  - Boat interiors
  - Areas under construction
- For use in homes, businesses or institutions.
- Contains no volatile organic compounds (VOC's)
- Contains no bleach, ammonia, alcohol or acid
- Odorless and colorless
- No fumes
- Not flammable
- Fungistat
- [Hard Surface] Fungistat
- Mildewstat
- [Hard Surface] Mildewstat
- [Cleans and][Controls][Prevents][Inhibits] the growth of [fungi][mildew][mold][mold and mildew] [and their odors] on [hard surfaces]
- Effective against [fungi][mildew][mold][mold and mildew]
- [Controls][Prevents][Inhibits] [fungi][mildew][mold][mold and mildew]
- Deodorizer
- CONCROBIUM is [specially formulated] [a unique technology] for effective [control] [elimination] of [most] offensive [stains] [odors] caused by mold and mildew.

---

Note: Bracketed[ ] information is optional text. Text separated by a comma(,) denotes—and/or—options.  
{Bracketed Text} is for administrative purposes only and will not appear on the printed label.

- Controls [Inhibits] mold and mildew [leaving a fresh clean scent] [leaving rooms clean and fresh smelling].
- Eliminates musty odors [caused by mold and mildew].

### **Directions for Use:**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

#### **READ LABEL BEFORE USING**

CONCROBIUM will not harm most surfaces. If in doubt, first perform a test application on a small, inconspicuous section of the surface in question. Do not use on surfaces vulnerable to water marks (such as leather or finished wood). If product contacts these surfaces, it should be wiped off immediately to prevent damage.

CONCROBIUM is designed to be used to prevent and inhibit the growth of mold, fungus and mildew on floors, walls, interior building surfaces, and other hard non-porous surfaces until such time as the cause of such growth can be identified and corrected. This product should be used in those cases where visible microbial growth has been detected (or conditions are likely to immediately result in such growth) as part of a program that removes that growth and identifies and corrects the conditions that led to that growth. As well, this product can be used to pre-treat building materials prior to being employed in a structure where an increase in the mold and fungus resistance of these materials would be desirable.

CONCROBIUM can be applied by hand-spray, paintbrush, roller, immersion, airless sprayer or pressure fogger (approximately 400 square feet per gallon). To maintain protection against re-growth, do not rinse or wash surfaces after treatment. Reapplication of CONCROBIUM may be required if surfaces are washed or painted or are otherwise directly exposed to water.

Ready to use—do not dilute.

#### **PREVENTATIVE TREATMENT**

To inhibit the growth of mold and mildew on surfaces:

- 1) Apply CONCROBIUM on area until evenly wet.
- 2) To promote drying and to avoid residue marks, use a clean cloth or paper towel to wipe off excess wetness.
- 3) Allow treated surfaces to dry completely.

## REMEDIAL TREATMENT

CONCROBIUM must be used as part of a comprehensive mold remediation or water damage restoration program, including:

- Periodic monitoring and inspection of conditions favorable to mold growth such as moisture ingress and high relative humidity
- Effecting repairs as necessary to eliminate conditions favorable to mold growth
- Drying of affected areas to below 20% moisture content

The following associations and Internet sites should be consulted for information on standards and guidelines for remedial treatment of mold and mildew:

- IAQA – Indoor Air Quality Association ([www.iaqa.org](http://www.iaqa.org))
- EPA – Environmental Protection Agency ([www.epa.gov](http://www.epa.gov))
- DOH – New York City Department of Health  
([www.ci.nyc.ny.us/html/doh/html/epi/moldrpt1.html](http://www.ci.nyc.ny.us/html/doh/html/epi/moldrpt1.html))
- IICRC – Institute of Inspection, Cleaning and Restoration Certification  
([www.iicrc.org](http://www.iicrc.org))

### Small Areas – Total Surface Area Affected Less Than 30 Square Feet

Areas of visible growth of less than 30 square feet (the area of a single wall panel) can normally be remediated without elaborate procedures. When these areas are identified, apply CONCROBIUM to retard growth and spread of fungal spores and other contaminants until the area can be thoroughly cleaned and remediated. If growth is on ceiling tiles or other such easily removable items of nominal value, remove them and seal them in a plastic bag and dispose with normal trash. If the surface is not easily replaceable:

- 1) Clean contaminated area to remove surface soil. For best results, and to avoid possible interference from other chemicals, use CONCROBIUM for initial cleaning. Use a cloth, cleaning pad or brush suitable to the durability of the surface being cleaned. Remove as much dirt and visible mold as possible.
- 2) Apply CONCROBIUM on cleaned area until evenly wet.
- 3) To promote drying and to avoid residue marks, use a clean cloth or paper towel to wipe off excess wetness.
- 4) Allow treated surfaces to dry completely.

Refer to the precautionary statements for the appropriate PPE to wear.



## **Large Areas – Total Surface Area Affected Greater Than 30 Square Feet**

Areas larger than 30 square feet require special procedures and individuals trained in remediation. Guidelines for remediation of large areas of contamination have been established by the Indoor Air Quality Associations ([www.iaqa.org](http://www.iaqa.org)) and the US Environmental Protection Agency ([www.epa.gov](http://www.epa.gov)). Many in the field also refer to the New York City Department of Health, "Guidelines on Assessment and Remediation of Fungi in Indoor Environments." Before using CONCROBIUM in mitigation of large projects, you should be knowledgeable of one or more of these guidelines and follow them when using the product. More information can be obtained from CONCROBIUM's web site ([www.concrobium.com](http://www.concrobium.com))

When water damage is suspected, the first priority is to find the source of water and cut it off. Once that has been accomplished, excess water should be removed. Detailed guidance on proper removal of excess levels of water is contained in, "Standard and Reference Guide for Professional Water Damage Restoration" (IICRC S500) published by the Institute of Inspection, Cleaning and Restoration Certification ([www.iicrc.org](http://www.iicrc.org)). If excess water has been removed completely in 24 hours or less, spraying surfaces that were wet with CONCROBIUM will inhibit growth and no other steps should be necessary.

Where structural members and/or contents have been exposed to water in excess of 24 hours, there is a possibility of extensive microbial growth that may be visible or hidden. In that case a complete assessment and remediation plan must be prepared that properly incorporates the use of CONCROBIUM, provides for user and occupant safety and documentation and monitoring of the remediation process. If you are not experienced in preparing and executing such a plan, contact CONCROBIUM Customer Service at (866) 811-4148 for assistance. IICRC S500 contains excellent guidance. In the context of such a plan, CONCROBIUM can be used on materials to be removed and disposed of and in other applications where an anti-microbial use is indicated.

Refer to the precautionary statements for the appropriate PPE to wear.

### **Personal Protection Equipment Requirements for Applicators**

For areas less than 30 sq. feet, an N-95 respirator, gloves and goggles/eye protection are recommended to avoid exposure to mold or mold spores. For areas greater than 30 sq. feet, an N-95 respirator or half-face respirator with HEPA filter, disposable overalls, gloves and goggles/eye protection.

### **Reapplication**

Repeat application weekly or when growth or odor reappears. Prior to reapplication determine the cause of re-growth and correct that problem prior to re-application. Reapplication of Concrobium may be required if surfaces are washed or painted or are otherwise directly exposed to water.

**STORAGE/DISPOSAL:** Do not contaminate water, food or feed by storage or disposal.

**PESTICIDE STORAGE:** Store in original container in areas inaccessible to small children. Keep securely closed.

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL:** Triple rinse (or equivalent). Then recycle or recondition, or puncture and dispose of in a sanitary landfill, or incinerate, or if allowed by state and local authorities, burn. If burned, stay out of smoke.

Lot No. XXXXXXXX

- Made in Canada
- Questions or Comments? Write:  
Customer Service,  
Siamons International Inc.,  
36 Meteor Road,  
Toronto, ON M9W 1A4

Visit our web site at [www.xxxxxxxxxx.com](http://www.xxxxxxxxxx.com)

*{Secondary container label for use if contents of 1 gallon label are placed in smaller containers}*

CONCROBIUM  
(Filled by user)

[Secondary Container Label]

Follow directions for use, storage and disposal from the [3.8L] [800 mL] [original]  
[CONCROBIUM] [container] label.

ACTIVE INGREDIENT

Trisodium Phosphate ..... 1.19%

OTHER INGREDIENTS..... 98.81%

TOTAL ..... 100.00%

EPA Reg. No. XXXXX-XXX



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

July 5, 2005

**MEMORANDUM**

**Subject:** Efficacy Review for EPA Reg. No. 82552-R, Concrobium  
DP Barcode: 318258

**From:** Tajah L. Blackburn, Ph.D., Microbiologist  
Efficacy Evaluation Team  
Product Science Branch  
Antimicrobials Division (7510C)

*[Signature]* 7/11/05

**Thru:** Nancy Whyte, Acting Team Leader  
Efficacy Evaluation Team  
Product Science Branch  
Antimicrobials Division (7510C)

*[Signature]*  
July 12, 2005

**To:** Adam Heyward PM 34/ Lisa McKelvin  
Regulatory Management Branch II  
Antimicrobials Division (7510C)

**Applicant:** Siamons International, Inc.  
Toronto, ON M9W 1A4

**Formulation from Label**

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Trisodium Phosphate.....	1.19%
<u>Other Ingredient(s)</u> .....	98.81%
Total	100.00%

## I BACKGROUND

The product, Concrobium (EPA Reg. No. 82552-R), is a new product. The applicant requested to register the product as a fungistat designed to prevent and inhibit growth of mold, fungus and mildew on floors, walls, and other hard nonporous interior building surfaces, until the cause of such growth is identified. Per the proposed label, "this product should be used in those cases where **visible microbial growth** has been detected (or conditions are likely to immediately result in such growth) as part of a program that removes that growth and identifies and corrects the conditions that led to that growth. "As current guidance directs, claims of this nature are considered non-public health. Therefore, efficacy data is reviewed and maintained on file; however performance standards are silent governing acceptance or rejection of efficacy data. Studies were conducted at umedik, Inc., located at 36 Meteor Drive, Toronto, Ontario, Canada, M9W 1A4.

This data package contained a letter from the applicant to EPA (dated May 27, 2005), two efficacy (MRID No. 465589-11 and -12), an Efficacy Discussion (MRID No. 465589-10), and the proposed label.

## II USE DIRECTIONS

This product is designed for use on floors, walls, and other **hard, nonporous** interior surfaces in basements, bathrooms, vacation homes, boat interiors, and areas under construction. Directions on the proposed label provided the following information regarding the use of the product:

Concrobium can be applied by hand-spray, paintbrush, roller, immersion, airless sprayer or pressure fogger (approximately 400 square feet per gallon). To maintain protection against regrowth, do not rinse or wash surfaces after treatment. Re-application of Concrobium may be required if surfaces are washed or painted or are otherwise directly exposed to water.

Preventive Treatment– To inhibit the growth of mold and mildew on surfaces: (1) Apply Concrobium on area until evenly wet; (2) To promote drying and to avoid residue marks, use a clean cloth or paper towel to wipe off excess wetness; (3) Allow treated surfaces to dry completely.

## III AGENCY STANDARDS FOR PROPOSED CLAIMS

Algaecides, slimicides, preservatives, deodorizers, and other products expressly claiming control of microorganisms of economic or aesthetic significance not directly related to human health do not require efficacy data. However, adequate dosage recommendations and complete directions for use must be provided on product label. These Agency standards are presented in DIS/TSS-16.

#### IV COMMENTS ON SUBMITTED EFFICACY STUDIES

**1. MRID No. 465589-11, "Fabric Mildew Fungistatic Test" for Siamons Mold Control, by Peter Lea, PhD. Study conducted at umedik, Inc. Study completion date— not disclosed. Experimental End Date— August 9, 2004.**

This study was conducted against *Aspergillus niger* (ATCC 6275) and *Penicillium variable* (ATCC 32333). Three lots were (Lot Nos. JJ040113-01/01/01, JJ040210-01/01/01, and JJ040628-01/01/02) of the product Siamons Mold Control were tested according to the test method as published in EPA's Pesticide Assessment Guidelines, Subdivision G: Product Performance, Section 93-15 (a) and 93-30 (I) (Item 1: Fabric Mildew Fungistatic Test Method, November 1982). Two lots (JJ040113-01/01/01 and JJ040210-01/01/01) were designated as the aged products (i.e., ≥60 days old). The product was received ready-to-use. The fungi were inoculated from stock cultures onto neopeptone agar plates and incubated at 25°C for eight days. Upon maturity, the spores were removed, and the suspensions were filtered through sterile cotton to remove the hyphae and hyphal fragments. Strips measuring 25 x 75 mm each were cut from unbleached cotton fabric. Each strip weighed ~ 0.27 grams (143.99 g/m<sup>2</sup>) to conform to the EPA guidelines. All strips were autoclaved, with a subsequent soak in glycerol nutrient solution for 3 minutes. Each fabric strip was dried under sterile conditions before use. Ten dried, nutrient saturated fabric strips per lot were evaluated. Using a spray bottle, each lot of Siamons Mold Control was sprayed 4 to 5 times on both sides, from a distance of 6-8 inches, onto the fabric strips. The strips were hung in the sterile laminar air flow hood. Ten untreated fabric strips were sprayed with saline solution in place of the test agent for the untreated control. All samples were allowed to dry before inoculation. Equal volumes of 5 x 10<sup>6</sup> conidia/ml suspension of *A. niger* and *P. variable* were mixed together and agitated. Each side of each fabric strips was lightly sprayed to inoculate the mixed conidial suspension using a DeVilbiss atomizer. The fabric samples were suspended in individual 500 ml jars containing approximately 90 ml sterile water, and incubated at 28±2°C. Observations were made and recorded weekly for 4 weeks (minimally 7, 14, 21 and 28 days). The presence or absence of observable mold on the fabric strips was the criterion for determining the efficacy of the test agent. When no visible growth was evident at the end of the test period, the fabric strips were examined microscopically. Controls included those for purity and sterility.

Note— Per the applicant's statement, "this study does not meet the requirements of 40 CFR Part 160 (Good Laboratory Practice Standards)."

Note— According to MRID No. 4655589-10, Siamons Mold Control is identical to Concrobium, the subject of the current efficacy review.

Note— The conidial recovery from inoculated fabric strips was not included in the efficacy report.

Note— No contact times were included in the efficacy report.

**2. MRID No. 465589-12, "Hard Surface Mildew Fungistatic Test" for Siamons Mold Control, by Peter Lea, PhD. Study conducted at umedik, Inc. Study completion date— not disclosed. Experimental end date— July 16, 2004.**

The study was conducted against *Aspergillus niger* (ATCC 6275). Three lots (Lot Nos. JJ040113-01/01/01, JJ040210-01/01/01, and JJ0404628-01/01/02) of the product, Siamons Mold Control, were tested using the were tested according to the method published in Pesticide Assessment Guidelines, Subdivision G: Product Performance, Section 93-15 (a) and 93-30 (I) (Item 2: Hard Surface Mildew Fungistatic Test Method, November 1982). Two lots (JJ040113-01/01/01 and JJ040210-01/01/01) were designated as the aged products (i.e.,  $\geq 60$  days old). The product was received ready-to-use. *A. niger* was inoculated from stock cultures onto neopeptone agar plates and incubated at  $25 \pm 2^\circ\text{C}$  for eight days. Upon maturity, the spores were removed and the suspensions were filtered through sterile cotton to remove hyphae and hyphal fragments. Ten carriers (glazed ceramic tiles) per lot were sprayed with the test substance using a spray bottle. Each tile was sprayed 4 to 5 times to ensure complete wetting. The distance from the nozzle of the spray bottle to a tile was 10 centimeters. Post spraying, the carriers were placed in a vertical or near vertical position in a separate Petri dish to permit excess liquid to drain. Five tiles were placed in each of two sterile Petri dishes with lids ajar and allowed to dry for 30 minutes at  $37^\circ\text{C}$ . Ten untreated tiles were placed in Petri dishes with lids ajar and allowed to dry at  $37^\circ\text{C}$ . Glazed ceramic carriers were inoculated with a  $5.0 \times 10^6$  conidia/ml, utilizing a #152 DeVilbiss atomizer while maintaining agitation. The tiles, located in Petri dishes, were returned to  $37^\circ\text{C}$  incubator and dried for 30 minutes until visibly dry. Carriers were subsequently placed in individual Petri dished containing harden sterile water agar for 7 days at  $25 \pm 2^\circ\text{C}$  with 95% humidity. Post incubation, the plates were observed for the presence or absence of macroscopic fungal growth. If no visible growth was evident at the end of the test period, the carrier was examined microscopically. Control included those for purity and sterility.

Note— Per the applicant's statement, "this study does not meet the requirements of 40 CFR Part 160 (Good Laboratory Practice Standards)."

Note— According to MRID No. 465589-10, Siamons Mold Control is identical to Concrobium, the subject of this current efficacy review.

Note— The conidial recovery from inoculated carriers was not included in the efficacy report.

Note— No contact times were included in the efficacy report.

## V RESULTS

Siamons Mold Control, Lot No. JJ040113-01/01/01 (>60 days old)

MRID Number	Organisms	Carrier Number	Test Results – Visual/Microscopic Growth/Carrier				Control Inoculum  (conidia/ml)
			Days				
			7	14	21	28	
465589-11	<i>A. niger</i>	1-10	0%	0%	0%	0%	5.0 x 10 <sup>6</sup>
	<i>P. variable</i>						5.1 x 10 <sup>6</sup>

Note– Untreated control 100% visual growth on carrier.

Saimons Mold Control, Lot JJ040210-01/01/01 (60 days old)

MRID Number	Organisms	Carrier Number	Test Results – Visual/Microscopic Growth/Carrier				Control Inoculum  (conidia/ml)
			Days				
			7	14	21	28	
465589-11	<i>A. niger</i>	1-10	0%	0%	0%	0%	5.0 x 10 <sup>6</sup>
	<i>P. variable</i>						5.1 x 10 <sup>6</sup>

Note– Untreated control 100% visual growth on carrier.

Siamons Mold Control, Lot JJ040628-01/01/02

MRID Number	Organisms	Carrier Number	Test Results – Visual/Microscopic Growth/Carrier				Control Inoculum  (conidia/ml)
			Days				
			7	14	21	28	
465589-11	<i>A. niger</i>	1-10	0%	0%	0%	0%	5.0 x 10 <sup>6</sup>
	<i>P. variable</i>						5.1 x 10 <sup>6</sup>

Note– Untreated control 100% visual growth on carrier.



MRID Number	Organism	Carrier Number	Test Results – Visual/Microscopic Growth/Carrier				Control Inoculum (conidia/ml)
			7 Days Exposure				
			JJ040112-01/01/01	JJ040210-01/01/01	JJ040628-01/01/02	Control	
465589-12	<i>A. niger</i>	1-10	0%	0%	0%	100%	5.0 x 10 <sup>6</sup>

## VI CONCLUSIONS

1. The submitted efficacy data (MRID 465589-11) **do not support** the use of the product Siamons Mold Control (ready-to-use), as a fungistat/mildewstat against *Aspergillus niger* and *Penicillium variable* on surfaces composed of fabric in the absence of a soil load for a unspecified contact period. The study was not conducted according to GLP guidelines/recommendations (40 CFR 160).
2. The submitted efficacy data (MRID 465589-12) **do not support** the use of the product Siamons Mold Control (ready-to-use), as a fungistat/mildewstat against *Aspergillus niger* on hard, non-porous surfaces in the absence of soil for an unspecified contact period. The study was not conducted according to GLP guidelines/recommendations (40 CFR 160).

## VII LABEL COMMENTS/RECOMMENDATIONS

1. The proposed label claims that the product, Concrobium, is an effective fungistat/mildewstat on hard, non-porous surfaces in the absence of soil for an unspecified contact period. **This claims is not acceptable. Studies were not conducted according to GLP guidelines/recommendations (40 CFR 160).** Additionally, as a measure of efficacy it is suggested that a minimal contact time consistent with the data be included on the label. Extended wetness is highly subjective, and lends to variable and multiple interpretations
2. The proposed label is silent regarding the use of the product on fabric surfaces. The use surfaces on the label refer to hard, non-porous surfaces. The use sites/surfaces should be expanded to include areas representative of "fabric surfaces".
3. Per Subdivision G: Section 93-30(I), "the directions for use must specify re-treatment every 7, 14, or 21 days, as necessary depending on the length of time that all of the test strips remain free of mildew growth. Labeling of products which do not permit growth after four weeks

incubation must specify a re-treatment schedule, such as repeat as necessary when new growth appears, and should indicate that treatments should be effective for at least 28 days.”



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

June 2, 2005

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

SIAMONS INTERNATIONAL, INC.  
PO Box 1014  
COLUMBIA CITY, IN 46725-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 31-MAY-05. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

PR Notice 86-5

31-MAY-05 Our staff has completed a preliminary analysis of the material.

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

PR Notice 86-5

31-MAY-05 Our staff has completed a preliminary analysis of the material.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

June 2, 2005

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT

OPP Decision Number: D-357584  
EPA File Symbol or Registration Number: **82552-R**  
Product Name: **CONCROBIUM**  
EPA Receipt Date: 31-May-2005  
EPA Company Number: 82552  
Company Name: SIAMONS INTERNATIONAL, INC.

SALLY HAYES  
SCIENTIFIC & REGULATORY CONSULTANTS, INC.  
SIAMONS INTERNATIONAL, INC.  
PO Box 1014  
COLUMBIA CITY, IN 46725

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for registration. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: **A54**

**NEW PRODUCT; NON-FAST TRACK; FIFRA SEC. 2(MM) USES**

Please remit payment in the amount of: **\$ 4,000** to:

By USPS:  
USEPA Washington Finance Center  
Pesticide Registration Service Fee  
PO Box 360277  
Pittsburgh, PA 15251

By Courier:  
U.S. EPA Washington Finance Center  
Pesticide Registration Service Fee  
C/O Mellon Client Service Center  
500 Ross Street, Room 670  
Box 360277  
Pittsburgh, PA 15251-6277  
Attn: EPA Module Supervisor  
Telephone: (412) 236-2294

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

You may be eligible for a full or partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is solely associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how to request and document a fee waiver is available on the OPP Fee for Service web site at [www.epa.gov/pesticides/fees](http://www.epa.gov/pesticides/fees).

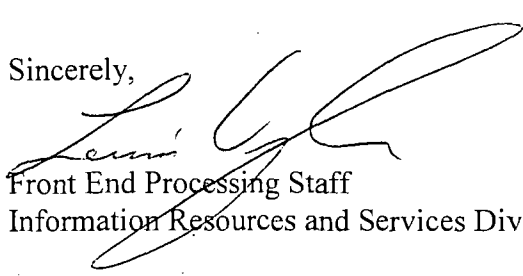
Please send Registration Service Fee Waiver requests to:

By USPS:  
Document Processing Desk (WAIVER)  
Office of Pesticide Programs (7504C)  
U.S. Environmental Protection Agency  
1200 Pennsylvania Ave NW  
Washington, DC 20460

By Courier:  
Document Processing Desk (WAIVER)  
Office of Pesticide Programs (7504C)  
U.S. Environmental Protection Agency  
Room 266A, Crystal Mall #2  
1801 S. Bell St.  
Arlington, VA 22202

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6432.

Sincerely,

  
Front End Processing Staff  
Information Resources and Services Division

# **SRC**

## **Scientific & Regulatory**

Consultants, Inc.

May 27, 2005

Mr. Adam Heyward, PM 34  
Document Processing Desk (APPL)  
Office of Pesticide Programs (7504C)  
U. S. Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1801 South Bell Street  
Arlington, VA 22202

SUBJECT: Concrobium  
EPA Reg. No.: *To be assigned*

Dear Adam,

On behalf of our client Siamons International, Inc. ("Siamons") enclosed is a submission for Concrobium. **This is the first US EPA registration for Siamons; an EPA company number needs to be assigned.** We will apply separately for an establishment number for the company that will manufacture Concrobium.

The active ingredient in Concrobium is trisodium phosphate (TSP). There is at least one product currently registered with EPA – Whizzer Mat Cleaner & Disinfectant, EPA Reg. No. 10118-1 – that contains TSP.

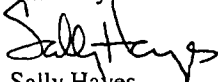
Concrobium is designed to be used to prevent and inhibit the growth of mold, fungus and mildew on floors, walls, and other hard non-porous interior building surfaces until such time as the cause of such growth can be identified and corrected. Such claims have traditionally been considered non-public health claims by the EPA. Nevertheless, we have enclosed two efficacy studies that demonstrate the efficacy of Concrobium.

As suggested by the Agency, we used two currently registered labels as guidance for preparing the Concrobium label. These labels used as models were BBJ Microbicide, EPA Reg. 67212-1 and Clorox F-40, EPA Reg. No. 72304-1.

Studies included with this submission call the product "Siamons Mold Control." This was an early name for the product and is identical in composition

You can contact me at (260) 244-6270 or shayes@srcconsultants.com if you need clarification or have any questions about this registration.

Sincerely,



Sally Hayes  
Agent for Siamons International, Inc.

cc: E. Green

# CONCROBIUM

EPA File Symbol XXX-xx

## TRANSMITTAL DOCUMENT

1. Name and address of submitter:

Scientific & Regulatory Consultants, Inc.  
PO Box 1014  
Columbia City, IN 46725

AGENT FOR:  
Siamons International, Inc.  
36 Meteor Drive  
Toronto, Ontario M9W 1A4

2. Regulatory action in support of which this package is submitted:

### REGISTRATION

3. Transmittal date: May 27, 2005

4. Vol. 1 Administrative materials:

- A) Cover letter
- B) Agent letter
- C) Application
- D) Certification with Respect to Citation of Data (EP)
- E) Data matrix (EP)
- F) Certification with Respect to Citation of Data (Active)
- G) Data matrix (Active)
- H) Confidential statement of formula
- I) Five (5) copies of labeling

46558901 5. Vol. 2 Product Chemistry

- A) OPPTS 830.1550-1800 Product Identity, Composition, and Analysis

46558902 6. Vol. 3 Product chemistry

- A) OPPTS 830.6302-7300 Product Properties

46558903 7. Vol. 4 Toxicity

- A) Toxicity discussion

46558904 8. Vol. 5 Toxicity

- A) OPPTS 870.1100 Acute Oral LD<sub>50</sub>

- 46558905 9. Vol. 6 Toxicity  
A) OPPTS 870.1200 Acute Dermal LD<sub>50</sub>
- 46558906 10. Vol. 7 Toxicity  
OPPTS 870.1300 Acute Inhalation
- 46558907 11. Vol. 8 Toxicity  
A) OPPTS 870.2400 Eye Irritation
- 46558908 12. Vol. 9 Toxicity  
A) OPPTS 870.2500 Skin Irritation
- 46558909 13. Vol. 10 Toxicity  
A) OPPTS 870.2600 Skin sensitization
- 46558910 14. Vol. 11 Efficacy Discussion  
A) Efficacy Discussion
- 46558911 15. Vol. 12 Efficacy  
A) Fabric Mildew Fungistatic Test
- 46558912 16. Vol. 13 Efficacy  
A) Hard Surface Mildew Fungistatic Test

Company Official: Sally Hayes

Company Name: Agent for Siamons International, Inc.

Company Contact: Sally Hayes



# CONCROBIUM

EPA File Symbol XXX-xx

## TRANSMITTAL DOCUMENT

1. Name and address of submitter:

Scientific & Regulatory Consultants, Inc.  
PO Box 1014  
Columbia City, IN 46725

AGENT FOR:  
Siamons International, Inc.  
36 Meteor Drive  
Toronto, Ontario M9W 1A4

2. Regulatory action in support of which this package is submitted:

### REGISTRATION

3. Transmittal date: May 27, 2005

4. Vol. 1 Administrative materials:

- A) Cover letter
- B) Agent letter
- C) Application
- D) Certification with Respect to Citation of Data (EP)
- E) Data matrix (EP)
- F) Certification with Respect to Citation of Data (Active)
- G) Data matrix (Active)
- H) Confidential statement of formula
- I) Five (5) copies of labeling

46558901 5. Vol. 2 Product Chemistry

- A) OPPTS 830.1550-1800 Product Identity, Composition, and Analysis

46558902 6. Vol. 3 Product chemistry

- A) OPPTS 830.6302-7300 Product Properties

46558903 7. Vol. 4 Toxicity

- A) Toxicity discussion

46558904 8. Vol. 5 Toxicity

- A) OPPTS 870.1100 Acute Oral LD<sub>50</sub>

- 48558905 9. Vol. 6 Toxicity  
A) OPPTS 870.1200 Acute Dermal LD<sub>50</sub>
- 48558906 10. Vol. 7 Toxicity  
OPPTS 870.1300 Acute Inhalation
- 48558907 11. Vol. 8 Toxicity  
A) OPPTS 870.2400 Eye Irritation
- 48558908 12. Vol. 9 Toxicity  
A) OPPTS 870.2500 Skin Irritation
- 48558909 13. Vol. 10 Toxicity  
A) OPPTS 870.2600 Skin sensitization
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A) Efficacy Discussion
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- 48558912 16. Vol. 13 Efficacy  
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- G) Data matrix (Active)
- H) Confidential statement of formula
- I) Five (5) copies of labeling

5. Vol. 2 Product Chemistry

- A) OPPTS 830.1550-1800 Product Identity, Composition, and Analysis

6. Vol. 3 Product chemistry

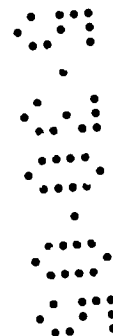
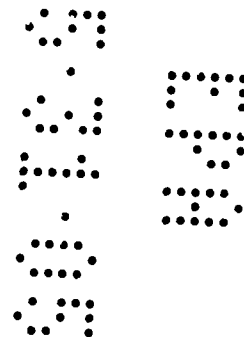
- A) OPPTS 830.6302-7300 Product Properties

7. Vol. 4 Toxicity

- A) Toxicity discussion

8. Vol. 5 Toxicity

- A) OPPTS 870.1100 Acute Oral LD<sub>50</sub>

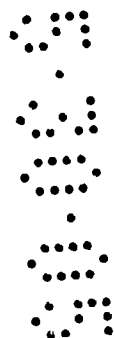
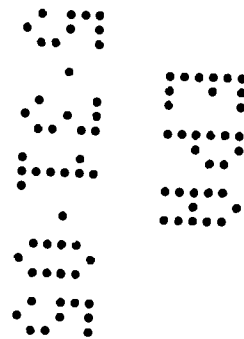


9. Vol. 6 Toxicity  
A) OPPTS 870.1200 Acute Dermal LD<sub>50</sub>
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OPPTS 870.1300 Acute Inhalation
11. Vol. 8 Toxicity  
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14. Vol. 11 Efficacy Discussion  
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16. Vol. 13 Efficacy  
A) Hard Surface Mildew Fungistatic Test

Company Official: Sally Hayes

Company Name: Agent for Siamons International, Inc.

Company Contact: Sally Hayes





United States  
Environmental Protection Agency  
Washington, DC 20460

☒ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number <del>XXX-XX</del> 82552-R	2. EPA Product Manager Adam Heyward	3. Proposed Classification  <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Concrobium	PM # 34	
5. Name and Address of Applicant (Include ZIP Code) Siamons International, Inc. 36 Meteor Drive Toronto, Ontario Canada M9W 1A4  <input type="checkbox"/> Check if this is a new address		6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 10118-1  Product Name Whizzer Mat Cleaner & Disinfectant

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

Concrobium (EPA File Symbol XXX-XX) uses an "old" active ingredient and existing use patterns (hard non-porous surfaces). This product is eligible for registration under PRIA code A54 (\$4,000 fee, 120-day review time).

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<input checked="" type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* <b>Certification must be submitted</b>		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 4 liter, 750 mL		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Label accompanying product	
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

## Section - IV

1. Contact Person (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Sally Hayes	Title Agent for Siamons International, Inc.	Telephone No. (Include Area Code) 260-244-6270
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped) 
2. Signature 	3. Title Agent for Siamons International, Inc.	
5. Typed Name Sally Hayes	4. Date May 27, 2005	



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

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**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Siamons International, Inc. 36 Meteor Drive Toronto, Ontario M9W 1A4 Canada 416-674-9500	EPA Registration Number/File Symbol XXX-XX
Active Ingredient(s) and/or representative test compound(s) EP - Trisodium phosphate	Date 05/27/05
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Prevent/ inhibit mold, fungus, mildew on hard non-porous surfaces	Product Name Concrobium

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulators Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
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**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method, or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Sally Haycs</i>	Date 05/27/05	Typed or Printed Name and Title Sally Haycs, Agent for Siamons International, Inc.
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401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date May 27, 2005			EPA Reg No./File Symbol XXX-XX		Page 1 of 3
Applicant's/Registrant's Name & Address Siamons International, Inc., 36 Meteor Drive, Toronto, Ontario, M9W 1A4, Canada			Product Concrobium		
Ingredient Trisodium phosphate (CAS 7601-54-9)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition	Not yet assigned	Siamons International, Inc.	Own	
830.1600	Description of Materials to Produce the Product	Not yet assigned	Siamons International, Inc.	Own	
830.1620	Description of Production Process	Not yet assigned	Siamons International, Inc.	Own	
830.1670	Discussion of the Formation of Impurities	Not yet assigned	Siamons International, Inc.	Own	
830.1700	Preliminary Analysis of Product Samples	Not yet assigned	Siamons International, Inc.	Own	
830.1750	Certified Limits	Not yet assigned	Siamons International, Inc.	Own	
830.1800	Enforcement Analytical Method	Not yet assigned	Siamons International, Inc.	Own	
830.6302	Color	Not yet assigned	Siamons International, Inc.	Own	
830.6303	Physical State	Not yet assigned	Siamons International, Inc.	Own	
830.6304	Odor	Not yet assigned	Siamons International, Inc.	Own	
830.6313	Stability	Waiver	Siamons International, Inc.		
830.6315	Flammability	Waiver	Siamons International, Inc.	Own	
830.6316	Explosibility	Waiver	Siamons International, Inc.	Own	
830.6317	Storage Stability	Not yet assigned	Siamons International, Inc.	Own	
830.6319	Miscibility	Waiver	Siamons International, Inc.	Own	
Signature 			Name and Title Sally Hayes, Agent for Siamons International, Inc.		Date May 27, 2005



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

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Applicant's/Registrant's Name & Address Siamons International, Inc., 36 Meteor Drive, Toronto, Ontario, M9W 1A4, Canada		Product Concrobium			
Ingredient Trisodium phosphate (CAS 7601-54-9)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Siamons International, Inc.	Own	
			Siamons International, Inc.	Own	
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			Siamons International, Inc.	Own	
			Siamons International, Inc.	Own	
			Siamons International, Inc.	Own	
			Siamons International, Inc.	Own	
Signature			Name and Title Sally Hayes, Agent for Siamons International, Inc.		Date May 27, 2005



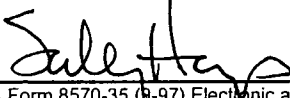


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Applicant's/Registrant's Name & Address Siamons International, Inc., 36 Meteor Drive, Toronto, Ontario, M9W 1A4, Canada			Product Concrobium		
Ingredient Trisodium phosphate (CAS 7601-54-9)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6320	Corrosion Characteristics	Not yet assigned	Siamons International, Inc.	Own	
830.6321	Dielectric Voltage Breakdown	Waiver	Siamons International, Inc.	Own	
830.7000	pH	Not yet assigned	Siamons International, Inc.	Own	
830.7100	Viscosity	Not yet assigned	Siamons International, Inc.	Own	
830.7200	Melting Point	Waiver	Siamons International, Inc.	Own	
830.7220	Boiling Point	Waiver	Siamons International, Inc.	Own	
830.7300	Density	Not yet assigned	Siamons International, Inc.	Own	
830.7370	Dissociation Constant	Waiver	Siamons International, Inc.	Own	
830.7550	Octanol/Water Partition Coefficient	Waiver	Siamons International, Inc.	Own	
830.7860	Solubility	Waiver	Siamons International, Inc.	Own	
830.7950	Vapor Pressure	Waiver	Siamons International, Inc.	Own	
870	Toxicity Discussion	Not yet assigned	Siamons International, Inc.	Own	
870.1100	Acute Oral Toxicity	Not yet assigned	Siamons International, Inc.	Own	
870.1200	Acute Dermal Toxicity	Not yet assigned	Siamons International, Inc.	Own	
870.1300	Acute Inhalation Toxicity	Not yet assigned	Siamons International, Inc.	Own	
Signature 			Name and Title Sally Hayes, Agent for Siamons International, Inc.		Date May 27, 2005



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Page 2 of 3

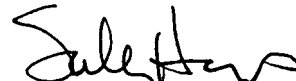
Applicant's/Registrant's Name & Address

Siamons International, Inc., 36 Meteor Drive, Toronto, Ontario, M9W 1A4, Canada

Product

Concrobium

Ingredient Trisodium phosphate (CAS 7601-54-9)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Siamons International, Inc.	Own	
			Siamons International, Inc.	Own	
			Siamons International, Inc.	Own	
			Siamons International, Inc.	Own	
			Siamons International, Inc.	Own	
			Siamons International, Inc.	Own	
			Siamons International, Inc.	Own	
			Siamons International, Inc.	Own	
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			Siamons International, Inc.	Own	
			Siamons International, Inc.	Own	
			Siamons International, Inc.	Own	
			Siamons International, Inc.	Own	
Signature 	Name and Title			Date	
Sally Hayes, Agent for Siamons International, Inc.			May 27, 2005		

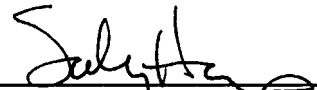


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Ingredient Trisodium phosphate (CAS 7601-54-9)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2400	Acute Eye Irritation	Not yet assigned	Siamons International, Inc.	Own	
870.2500	Acute Dermal Irritation	Not yet assigned	Siamons International, Inc.	Own	
870.2600	Skin Sensitization	Not yet assigned	Siamons International, Inc.	Own	
Subdivision G: 93-15(a)	Efficacy Discussion	Not yet assigned	Siamons International, Inc.	Own	
Subdivision G: 93-15(a)	Fabric Mildew Fungistatic Test	Not yet assigned	Siamons International, Inc.	Own	
Subdivision G: 93-15(a)	Hard Surface Mildew Fungistatic Test	Not yet assigned	Siamons International, Inc.	Own	
Signature 			Name and Title Sally Hayes, Agent for Siamons International, Inc.		Date May 27, 2005

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy



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WASHINGTON, D.C. 20460

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Applicant's/Registrant's Name & Address Siamons International, Inc., 36 Meteor Drive, Toronto, Ontario, M9W 1A4, Canada	Product Concrobium	

Ingredient Trisodium phosphate (CAS 7601-54-9)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Siamons International, Inc.	Own	
			Siamons International, Inc.	Own	
			Siamons International, Inc.	Own	
			Siamons International, Inc.	Own	
			Siamons International, Inc.	Own	
			Siamons International, Inc.	Own	

Signature 	Name and Title Sally Hayes, Agent for Siamons International, Inc.	Date May 27, 2005
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**WASHINGTON, D.C. 20460**

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**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Siamons International, Inc. 36 Metcor Drive Toronto, Ontario M9W 1A4 Canada 416-674-9500	EPA Registration Number/File Symbol XXX-XX
Active Ingredient(s) and/or representative test compound(s) Trisodium phosphate	Date 05/27/05
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Prevent/ inhibit mold, fungus, mildew on hard non-porous surfaces	Product Name Concrobium

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulators Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

<input checked="" type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
---	--

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method, or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 05/27/05	Typed or Printed Name and Title Sally Hayes, Agent for Siamons International, Inc.
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date May 27, 2005

EPA Reg No./File Symbol XXX-XX

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Applicant's/Registrant's Name & Address

Siamons International, Inc., 36 Meteor Drive, Toronto, Ontario, M9W 1A4, Canada

Product

Concrobium

Ingredient Trisodium phosphate (CAS 7601-54-9)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			See attached list	Pay	

Signature *Sally Hayes*

Name and Title

Sally Hayes, Agent for Siamons International, Inc.

Date

May 27, 2005

076403 Sodium phosphate (Na<sub>2</sub>H(PO<sub>4</sub>))

COMPANY# 001266 MALTER INTERNATIONAL CORPORATION  
\* DATA TYPES \* PO BOX 6099  
EU AT EC FW EF OT NEW ORLEANS, LA 70174  
XX XX

COMPANY# 001696 METRO PRODS COMPANY  
\* DATA TYPES \* 4720 FREDERICK DR SW  
EU AT EC FW EF OT ATLANTA, GA 30336  
XX XX

COMPANY# 002155 I. SCHNEID  
\* DATA TYPES \* PO BOX 16247  
EU AT EC FW EF OT ATLANTA, GA 30321  
XX

COMPANY# 009092 EKCO CHEMICAL PRODUCTS COMPANY  
\* DATA TYPES \* 302 5TH AVENUE  
EU AT EC FW EF OT MOLINE, IL 61265  
XX

COMPANY# 010852 SCIENTIFIC PACKAGING CORPORATION  
\* DATA TYPES \* 1502 NICOLLET AVENUE, #27  
EU AT EC FW EF OT MINNEAPOLIS, MN 55403  
XX

CHEMICAL CHEMICAL NAME  
076404 Sodium tripolyphosphate

COMPANY# 004829 COASTAL INDUSTRIES  
\* DATA TYPES \* 225 PASSAIC STREET  
EU AT EC FW EF OT PASSAIC, NJ 07055  
XX

COMPANY# 005741 SPARTAN CHEMICAL COMPANY, INC.  
\* DATA TYPES \* 1110 SPARTAN DRIVE  
EU AT EC FW EF OT MAUMEE, OH 43537  
XX

COMPANY# 006097 OLYMPIC MFG COMPANY  
\* DATA TYPES \* PO BOX 19508  
EU AT EC FW EF OT ATLANTA, GA 30325  
XX

CHEMICAL CHEMICAL NAME  
076405 Tetrasodium pyrophosphate

COMPANY# 071094 MICROCID INC  
\* DATA TYPES \* 2209 NIAGARA DR  
EU AT EC FW EF OT TROY, MI 48083  
XX

CHEMICAL CHEMICAL NAME  
076406 Trisodium phosphate

COMPANY# 000178 PURDY PRODUCTS COMPANY  
\* DATA TYPES \* PO BOX 456  
EU AT EC FW EF OT WAUCONDA, IL 60084  
XX XX



COMPANY# 001266 MALTER INTERNATIONAL CORPORATION  
\* DATA TYPES \* PO BOX 6099  
EU AT EC FW EF OT NEW ORLEANS, LA 70174  
XX XX

COMPANY# 001778 WESTERN CHEM COMPANY  
\* DATA TYPES \* 615 ALBEMARLE STREET  
EU AT EC FW EF OT ST JOSEPH, MO 64502  
XX

COMPANY# 003573 THE PROCTER & GAMBLE COMPANY  
\* DATA TYPES \* 5299 SPRING GROVE AVENUE  
EU AT EC FW EF OT CINCINNATI, OH 45217  
XX XX XX

COMPANY# 003813 CROUCH SUPPLY COMPANY INC  
\* DATA TYPES \* PO BOX 163829  
EU AT EC FW EF OT FT WORTH, TX 76161  
XX

COMPANY# 006097 OLYMPIC MFG COMPANY  
\* DATA TYPES \* PO BOX 19508  
EU AT EC FW EF OT ATLANTA, GA 30325  
XX XX

COMPANY# 010118 MUELLER SPORTS MEDICINE INC.  
\* DATA TYPES \* PO BOX 99  
EU AT EC FW EF OT PRAIRIE DU SAC, WI 53578  
XX XX XX XX

COMPANY# 010852 SCIENTIFIC PACKAGING CORPORATION  
\* DATA TYPES \* 1502 NICOLLET AVENUE, #27  
EU AT EC FW EF OT MINNEAPOLIS, MN 55403  
XX

COMPANY# 011602 MOLAR ENTERPRISES  
\* DATA TYPES \* 1621 HENNEPIN AVE  
EU AT EC FW EF OT MINNEAPOLIS, MN 55430  
XX

COMPANY# 013285 PCI OF AMERICA  
\* DATA TYPES \* 10683 WAKEMAN COURT  
EU AT EC FW EF OT MANASSAS, VA 20110  
XX XX XX

CHEMICAL 076407 CHEMICAL NAME  
Potassium phosphate, tribasic

COMPANY# 000334 HYSAN/AMP  
\* DATA TYPES \* 9055 FREEWAY DRIVE  
EU AT EC FW EF OT MACEDONIA, OH 44056  
XX

COMPANY# 003573 THE PROCTER & GAMBLE COMPANY  
\* DATA TYPES \* 5299 SPRING GROVE AVENUE  
EU AT EC FW EF OT CINCINNATI, OH 45217  
XX XX XX

CHEMICAL 076409 CHEMICAL NAME  
Monosodium phosphate

